UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
15-cv-2210 (PJS/BRT)

RONALDO LIGONS, et al.,

Plaintiffs,

v.

MINNESOTA DEPARTMENT OF CORRECTIONS et al.,

Defendants.

# PLAINTIFFS' UNIFIED MEMORANDUM:

## IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT;

## IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO LIABILITY ON THE STANDARD OF CARE;

## IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION;

## IN SUPPORT OF PLAINTIFFS' MOTION TO CERTIFY CLASSES PER FED. R. CIV. P. 23;

## AND IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT REPORT OF NEWTON KENDIG, M.D., PER *DAUBERT v. MERRELL DOW.*

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# INTRODUCTION

A. Defendants' Jan. 2016 Protocols Reveal Continuing Deliberate Indifference

This case began on 1 May 2015 with Defendants' institutional HCV treatment protocol falling short of the AASLD/IDSA standard of medical care, with interferon and chemical dependency treatment the norm. Dr. Paulson admitted prior knowledge of the AASLD/IDSA standard on 3 March 2015.

Less than one month after the 4 January 2016 deadline for amending the pleadings and joining additional parties, Defendants enacted a new HCV treatment protocol that fell short of the known AASLD/IDSA professional standard of medical care of treating all infected, by treating only liver-damaged FIB3-4[1] HCV inmates with DAAs -- at Dr. Paulson's sole discretion – and leaving the majority of infected inmates untreated.

Defendants plead mootness after choosing to treat Plaintiffs Ronaldo Ligons in February 2017, and releasing Barry Michaelson in March 2017. Equity prohibits the Defendants from changing the facts on the ground and then using procedural tricks as a sword and a shield for Defendants' ongoing deliberate indifference. Lawrence Maxcy and Devon Farley are members of the class of long-term, HCV-infected inmates represented by Mr. Ligons and Mr. Michaelson. Mr. Farley exhausted his administrative remedies in March 2017, Mr. Maxcy in 2015. Messrs. Ligons, Michaelson, Maxcy, and Farley are living proof that the Defendants' ongoing unconstitutional, deliberately indifferent denial of the

[1] Fibrosis "FIB4" score measures liver scarring from 0 no scarring to 4 at cirrhosis.

AASLD/IDSA standard of HCV medical care is not moot, but is "capable of repetition while evading review."[2]

B. Why Medical Deliberate Indifference to the Standard of Care is "Different."

In most §1983 cases, government officials turn to facts in caselaw for the standard of law enforcement constitutional care, to respect individuals' rights and not lose qualified immunity. In medical cases, courts turn to expert doctors, to find the standard of professional medical care the Constitution guarantees to prisoners. The recent development of direct-acting antiviral medicines (DAAs) to cure Hepatitis C (HCV) at 95%+ is to Hepatitis C what the Salk-Sabin vaccine was to polio.

C. The AASLD/IDSA Standard of Care for HCV

Whether the AASLD/IDSA[3] standard of Hepatitis C[4] professional medical care – to treat every HCV infection with 95%+ curative direct-acting antiviral (DAA) medicines – applies to the Plaintiffs and Minnesota's prisons, or not, is the question before the Court. Defendants' unconstitutional, deliberate indifference to the serious medical needs of Plaintiffs, who are infected with HCV, to be treated in accordance with the AASLD/IDSA professional standard of care, and the serious medical needs of the Plaintiffs who are

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[2] *Roe v. Wade*, 410 U.S. 113, 125 (1973), *Honig v. Doe*, 484 U.S. 305, 335-36 (1988) (noting exceptions for mootness "upon the great likelihood that the issue will recur *between the defendant and the other members of the public at large"* and class actions).

[3] American Association for the Study of Liver Disease/Infectious Disease Society of America; see www.hcvguidelines.org. Exceptions include co-morbidities with six month or less life expectancies. Treatment requires 84 straight days of one pill per day.

[4] Hepatitis C (HCV) is a chronic, but curable disease of the digestive and circulatory systems that substantially impairs a patient's digestion, mobility, thinking, social interaction, and procreational major life activities; untreated, HCV causes permanent liver fibrosis, cirrhosis, liver cancer, and death by liver failure.

uninfected or are being cured, and want to stay uninfected, violates the Eighth Amendment with respect to prison conditions.

D. Contractual Violation of Equal Protection, the ADA Title II and §504.

The Defendants' discriminatory denial of the AASLD/IDSA *twelve-week* standard of medical care to the Plaintiffs because of their curable HCV infection, in contrast to Defendants' contractual provision of the prevailing Twin Cities standard of *lifetime chronic management* medical care to prisoners infected with the incurable human HIV/AIDS, violates the Plaintiffs' Fourteenth Amendment Equal Protection rights, and their ADA Title II and §504[5] rights to be free from discriminatory denial of the professional standard of medical care because of their disability, HCV.

E. Summary of Arguments

1. The Court must deny summary judgment to the Defendants for the following reasons:

(a) Genuine, material disputed facts address applicability the AASLD/IDSA medical standard of HCV care to HCV-positive prison inmates;

(b) Genuine issues of material fact are in dispute regarding the sufficiency of the HCV "corrections standard" Defendants and expert Dr. Kendig advance;

(c) The admissibility of Dr. Kendig's non-medical "correctional" HCV standard-of-care is in dispute, under the *Daubert* test, as well;

(d) Genuine, disputed material facts exist as to Dr. Paulson's claim that he knows of no instance of inmate-to-inmate infection;

[5] Title II of the Americans with Disabilities Act as Amended, 42 U.S.C. §12131 et seq. (2008), and §504 of the Rehabilitation Act of 1973, 29 U.S.C. §§791-794a.

(e) Genuine, disputed facts exists as to Defendants' individual and institutional demonstration of deliberate indifference to the serious medical needs for HCV treatment of: (i) Plaintiffs Ligons in the delayed treatment after exhaustion of remedies, (ii) Plaintiff Michaelson, in view of his documented exposure to HCV-infected blood of his cellmate and the refusal to counsel or treat Mr. Michaelson in accordance with federal, state, laws, regulations, and directives, and (iii) Maxcy and Farley in the denied treatment after exhaustion of administrative remedies.

2. Plaintiffs have made the case for preliminary injunction to strike down the existing MN DOC treatment protocol and replace it with a protocol that treats all HCV-infected inmates in accordance with the AASLD/IDSA standard of care.

3. Plaintiffs have satisfied the requirements of numerosity, typicality, commonality, and adequacy for class certification. See class certification of HCV-infected inmates of the Massachusetts Department of Corrections, *Fowler v. Turco*, 15-cv-12298 (D. Mass. July 22, 2016), ECF48, and pending class certification in Tennessee, *Graham v. Parker*, 16-cv-1954 (Order, D. M.D. Tenn. Feb. 27, 2017), ECF28, with that Court's open acknowledge of the need for medical monitoring as a remedy ("However, given the nature of the case, settlement discussion will of necessity involve medical personnel and potentially the need for monitoring by some designated agency[,]") drive the stake into the Defendants' arguments against class certification under the PLRA.

4. Dr. Kendig's expert witness report invades the province of the Court in its substitution of constitutional analysis of *Estelle v. Gamble*. Dr. Kendig admits that he would treat his own patients in accordance with the AASLD/IDSA standard of care.

Defendants' expert opinion does not withstand scrutiny under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), or *Kumho Tire v. Carmichael,* 526 U.S. 137 (1999).

## I. MATERIAL, DISPUTED FACTS REQUIRE DENIAL OF DEFENDANTS' MOTION UNDER RULE 56 AND QUALIFIED IMMUNITY.

Fed. R. Civ. P. 56(c) allows summary judgment if the record shows, "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The movant has the burden of production and proof. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Genuine issue of material fact exists when "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986), *Graves v. Arkansas Dep't of Fin. & Admin.*, 229 F.3d 721, 723 (8th Cir. 2000), *Nelson v. Corr. Med. Servs.,* 583 F.3d 522, 525 (8th Cir. 2009) (en banc) (qualified immunity denied in 8th Amendment case of shackled prisoner in labor, citing *Liberty Lobby* at 255).

The Eighth Amendment "prohibits the infliction of cruel and unusual punishments on those convicted of crimes." *Wilson v. Seiter*, 501 U.S. 294, 296-97 (1991). A prison official is deliberately indifferent if she "knows of and disregards" a serious medical need or a substantial risk to an inmate's health or safety. See *Farmer v. Brennan*, 511 U.S. 825, 837 (1994). "[I]t is enough that the official acted or failed to act despite [her] knowledge of a substantial risk of serious harm," *Farmer*, 511 U.S. at 842, quoted in *Nelson*, 583 F.3d at 529, and it "is a question of fact subject to demonstration in the usual ways, including inference from circumstantial evidence, and a factfinder may conclude that a prison official knew of a substantial risk from the very fact that the risk was obvious." Id.

Determination of the proper treatment of a serious medical need turns upon the standard of care that governs specialty doctors in the relevant branch of medicine, not government regulations or self-referential criteria. *U.S. v. Kubrick*, 444 U.S. 111, 123 (1979). See *Heard v. Sheahan*, 253 F.3d 316, 318 (7th Cir. 2000)(Posner, Richard, J.) (reversing dismissal of Eighth Amendment denial of medical care case; "[T]he suit charges that the defendants inflicted cruel and unusual punishment on the plaintiff by refusing to treat his condition. This refusal continued for as long as the defendants had the power to do something about his condition, which is to say until he left the jail[]").

Plaintiffs' major claims include: (a) deliberate indifference in failing to treat HCV-positive inmates under *Erickson v. Pardus,* 551 U.S. 89 (2007), by refusing to apply the medical community standard of care consistent with the AASLD/IDSA HCV guidelines in the manner described in *Kubrick*, supra, and (b) exposing uninfected inmates to life-threatening infectious disease under *Helling v. McKinney*, 509 U.S. 25, 33 (1993).

Qualified immunity protects government officers from §1983 liability "unless the official's conduct violates a clearly established constitutional or statutory right of which a reasonable person would have known." *Nelson*, 583 F.3d at 527. Courts perform a three-step inquiry to determine if qualified immunity applies by determining: (1) whether the facts show the violation of a constitutional or statutory right, *Tolan v. Cotton*, 572 U.S. at ___, 134 S. Ct. 1861, 1865 (2014) (qualified immunity denied; four material disputed facts between plaintiff and police) and (2) whether that right was clearly established at the time of the alleged misconduct. *Saucier v. Katz*, 533 U.S. 194, 201 (2001), *Brown v. City of Golden Valley*, 574 F.3d 491, 496 (8th Cir. 2009) (either step first).

Supreme Court precedent, circuit court precedent, governing regulations of a law enforcement agency, and relevant reports of government agencies define the contours of clearly established law and clearly established duties to obey the law. *Hope v. Pelzer*, 536 U.S. 730, 741 – 44 (2002). Defining "clearly established law" in the "specific context of the case" prohibits definition of "context" that "imports genuinely disputed factual propositions." *Tolan* at 1865-66. Defining "clearly established law" in a manner that ignores genuine, outcome-determinative factual disputes, incorporates the movant's proposed factual findings into the contours of "governing" law, ignores contradictory admissible evidence, and improperly "weighs" evidence commits reversible error. U.S. Const. amend. VII, *Tolan*, 134 S. Ct. at 1865, citing *Anderson*, 477 U.S. at 249.

The third step requires the court to determine whether there exists a "genuine issue of fact as to the objective reasonableness of the officer's conduct in light of the law and the information the officer possessed at the time." See *Adewale v. Whalen*, 21 F.Supp.2d 1006, 1013 (D. Minn. 1998) (Tunheim, J.) (summary judgment denied in excessive force case).

For the Court's convenience, Plaintiffs track the Defendants' memorandum to defeat their Motion – and set forth additional, material facts.

**A. The Parties, ECF106:2 -- Disputed**[6]

It is disputed that Defendant Nanette Larson is *only* a "hospital administrator." Dr. Paulson reports to Nanette Larson, she is his supervisor, (Paulson Aff. ¶7) and is ultimately responsible for the entire DOC medical staff. (Larson Dep. 13:1-25). Larson identified

[6] ECF106:2 is nomenclature for docket #106, Defendants' memo, page 2.

herself as the top of the "kite" and grievance "chain of command" (Larson Aff. ¶9). Her signature appeared with comments on replies and correspondence involving appeals of treatment decisions from the DOC head office, including named Plaintiffs. (Larson Dep. pp.14,18 ) Dr. Paulson "assists" Nanette Larson on "kites" and grievances. (Paulson Aff. ¶7). Ms. Larson administers the contracts with Centurion Managed Care. (Paulson Aff. Ex. B. Larson Dep. pp. 13-14, Larson Aff. ¶¶ 6-7).

**B. Medical Care at the Dep't of Corrections, ECF106:3 - DISPUTED**

Dr. Paulson admits delaying prescribing DAA medication without ever examining or speaking to a single patient, then assisting Larson with "kites" and grievances. (Paulson Aff. ¶¶7-8). The AASLD/IDSA standard of care cited by Dr. Paulson's Affidavit emphasizes that the standard-of-care is treating all HCV-positive patients. See, *http://www.hcvguidelines.org.* (updated: July 6, 2016) (Paulson Aff. Ex. H):

> ".... When the FDA approved the first IFN sparing treatment for HCV infection, many patients who had previously been "warehoused" sought treatment, and the infrastructure (experienced practitioners, budged healthcare dollars, etc) did not yet exist to treat all patients immediately. *Thus the panel offered guidance for prioritizing treatment first to those with the greatest need.* Since that time, there have been opportunities to treat many of the highest risk patients and to accumulate real world experience of the tolerability and safety of the newer HCV medications.... Therefore the panel continues to recommend treatment for all patients with chronic HCV infection.... *Accordingly prioritization tables are now less useful and have been removed from this section."* (emphasis added)

The end of AASLD/IDSA sanctioned prioritization signaled the end of the scarcity that characterized the "breakthrough" drugs from their FDA approval at the end of 2013 to June 29, 2015 when the AASLD/IDSA announced the end of prioritization and eliminated references to its use. (see discussion, *supra*). (See comparison between AASLD/IDSA

recommendations between December 19, 2014 (Paulson Aff. Ex. D) and July 6, 2016 (Paulson Aff. Ex. H).

Defendants have already acknowledged that the medical community standard of care must be provided to HIV/AIDS-positive prisoners, as reflected the current Contract #70449 between the Minnesota Department of Corrections (MNDOC) and private medical care contractor (Centurion of Minnesota) demonstrates MNDOC knowledge that such a standard exists *outside* the "correctional context" and *within* the medical profession. Failing to provide the HCV medical standard of care is, therefore, intentional, not negligent.

> CONTRACT #70449
>
> Attachment 1: On Site Services
>
> H. HIV SERVICES
> The CONTRACTOR (*i.e.* Centurion) shall provide all treatment of HIV/AIDS in a manner *consistent with applicable standards of medical care, including CDC guidelines and Twin Cities' area community standard of care...* (emphasis added)
>
> P. HEPATITIS C TREATMENT
> The CONTRACTOR (*i.e.* Centurion) shall provide services for the diagnosis and treatment of Hepatitis C within the *then current guidelines* and the current Hepatitis C treatment *protocols established by the DOC*, as incorporated herein by reference for the diagnosis and treatment protocols· *established by the DOC*, as incorporated herein by reference. This includes requirements perform liver biopsies, lab tests, medications, and ·psychiatry, and may change from time-to-time *at the discretion of the DOC* (emphasis added.

ECF93, Ex. A (Rebuttal Declaration of Dr. Thompson, Ex. A).

Defendants acknowledge the treatment of HIV/AIDS must be "in a manner consistent with applicable standards of medical care, including CDC guidelines and the Twin Cities

area community standard of care...." thus admitting mutual obligation to provide medical care at a level beyond the self-referential "correctional standard of care" to which Dr. Kendig's Report is directed and the contract permits for HCV treatment by exception to *Estelle v. Gamble,* 429 U.S. 97 (1976). Defendants can cite no "rational basis" or medical justification for applying differing standards to two potentially fatal, blood-borne viral diseases, HIV/AIDS and HCV, very often residing in the same patient.

According to Nanette Larson, there are also "practice agreements" between DOC and certified nurse practitioners and or physicians assistants employed by the DOC, which requires them to provide the "same type and level of care as a regular physician." (Larson Aff. ¶6). Plaintiffs assert that, standing alone, this contractual distinction makes out the facts for violations of both deliberate indifference to the AASLD/IDSA standard-of-care and equal protection under the fourteenth amendment, on its face. And, "genuine issues of material fact" do lie if a jury could conclude for Plaintiff based on "all reasonable evidence to be drawn from those facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.* 475 U.S. 574, 587 (1986) a Rule 56 Motion does not properly lie.

## C. Hepatitis C, ECF106:4 -- DISPUTED

Because the entire discussion of HCV is based on self-referential cites to either Dr. Paulson or Dr. Kendig throughout this section, every conclusion is factually at issue by reference to the AASLD/IDSA Guidelines website: *http://hcvguidelines.org*. Dr. Kendig concedes that, outside of the prison context, he would not use the "correctional" standard of care for private patients that he is advocating for prisoner-patients:

Q. Would you use the correctional standard of care for treating Hepatitis C patients in a private clinical setting in 2016?

A. *NO* (Kendig Dep. p.25) (emphasis added)

In particular, also Dr. Paulson claims never to have "heard of HCV transmission between inmates or between inmates and DOC staff." (Paulson Aff. ¶11, Paulson Dep. 78-81, ECF106:5. This is in dispute, as is Dr. Paulson's credibility because both named Plaintiffs in this case (Mr. Ligons and Mr. Michaelson, were infected while inmates, either by other inmates or staff practices). ECF42, Ligons Dep. 14:14-23, Michaelson Dep. 6:4-7, 22:6-9.

Neither Dr. Kendig nor Dr. Paulson acknowledge that prison, itself, is listed by AASLD/IDSA as a risk for HCV exposure because such a high percentage of inmates are HCV-positive and opportunities for risk-related infection are greater than a "household" setting. Thompson Decl., ECF79, Ex. A. D. G. and J, ECF93 (rebuttal), Paulson Aff. ¶ 10. Dr. Paulson admitted that cellmates could pass HCV one to the other through sex in prison, or cleaning up blood spills from another inmate. Paulson Aff. Ex. A, Paulson Dep. p. 81. The CDC has noted the particular hazards associated with incarceration of HCV exposure because of the large percentage of HCV-positive inmates in prison populations and risky behavior related to incarceration. Pub. No. 21-1306, *Hepatitis C and Incarceration* ECF79, Ex. J.

**D. Screening for Hepatitis C. ECF106:5 -- DISPUTED**

Nanette Larson asserts that about 77 MNDOC inmates have been treated under the "prioritization" protocols in place since no later than January 2016. Larson Aff. ¶14,

ECF106, 21. However, the Paulson Deposition states that only approximately ten (10) MNDOC inmates have been treated for HCV. (Paulson Dep. p. 41). An average sentence is 45 months and 17,000 unique individuals are incarcerated during a calendar year. Larson Aff. ¶14. Ten to 35 percent HCV-positive, according to national estimates (1000 to 3500) of the estimated 9,000 to 10,000 inmates under the supervision of MNDOC are currently infected with HCV. See, *Health Services Unit*, "Chronic Hepatitis C Management & Procedures, 5/9/2012 - distributed June 2015).[7] Contradictions between the Defendants' own witnesses regarding the efficacy of the HCV screening and treatment program demonstrate a triable deliberate indifference issue.

The two step-antibody screening process described is not at issue. The treatment of the estimated 3,500 HCV-positive patients, who remain HCV-positive under the current MNDOC protocols, remains the unresolved issue requiring injunctive relief. The FBOP Guidelines and MNDOC January 2016 Guidelines do not meet the AALSD/IDSA standard-of-care, of which there is no dispute between the parties. ECF106:22. The question is whether the failure to adhere to the medical standard-of-care for a deadly, but now curable infectious disease, is lawful.

Defendants dispute whether cost of treatment *is*, or may be, an issue under the Eighth Amendment. ECF106:22-23, citing *Cramer v. Iverson*, Civ. No. 07-cv-725 (DWF/SRN) 2008 WL 4838715, at*5 n.8 (D. Minn. Nov. 5 ,2008); *Dulany v. Carnahan*, 132 F.3d 1234

[7] Defendants claim April 2015 HCV Guidelines were issued "in response to the new crop of DAAs," ECF106:8. However, the documentary record shows Plaintiffs were provided the document marked June 2015, referring to 2012. There is a factual dispute whether MNDOC actually promulgated 2015 standards before January 2016.

(8th Cir. 1997); *Thompson v. King*, 730 F.3d 742 (8th Cir. 2013); *Cullor v. Baldwin*, 830 F.3d 830 (8th Cir. 2016). However, capping the HCV budget for Centurion at $3,000,000 has the effect of imposing cost-based rationing into the HCV treatment calculation, Larson Aff. ¶¶ 11-16), incompatible with the Eight Amendment prohibition against cruel and unusual punishment by willful, intentional denial of necessary medical care, *Estelle,* 429 U.S. at 105-06, Wilson *v. Seiter*, 501 U.S. 294, 303-04 (1991). This presents a triable issue of fact. *Matsushita,* 475 U.S. at 587.

## E. Medical Monitoring of HCV Patients, ECF106:6 DISPUTED

This section is full of conclusions about the speed at which HCV infection advances that, according to AASLD/IDSA, http://www.hcvguidelines.org., and experts of Plaintiff is not predictable. See Dr. Thompson Dep. 35:10-24, Dr. Cecil Dep. 22:7-22 (fast progression: "surprises"), ECF79, and ECF93.

There is no dispute that Defendants: (1) *know* that their HCV-positive patients will likely experience deterioration of their liver which may be life threatening; (2) *observe* the physical deterioration and scarring of their HCV patients' liver to "prioritize treatment"; (3) *cure* the virus only *after* they have *observed predicted liver deterioration*; (4) in so doing, Defendants admit their "Medical Monitoring" ECF106:6-7) must be "deliberately indifference" to the deterioration of the liver prior to administering the DAA cure, even though a cure is now available the entire time the patient is HCV-positive at any fibrosis level. *Estelle v. Gamble*, 429 U.S. 97, 104-105 (1976); *Farmer v. Brennan*, 511 U.S. 825, 834 (1994). Thus, a jury could find the intentional refusal to provide standard-of-care

DAA medication is "so inappropriate as to evidence intentional maltreatment," *Jolly v. Knudsen*, 205 F.3d 1094, 1096 (8th Cir. 2000), *Anderson*, 477 U.S. at 255.

The Defendants also admit that by failing to treat HCV-positive inmates until they reach the F3-F4 FIB-score, the majority of the 1000 to 3500 HCV-positive inmates in MNDOC will remain a risk of infection to uninfected prisoners, including those who have already been cured such as Mr. Ligons. The Supreme Court has long recognized that infection with the Hepatitis-C virus (HCV) is a serious medical need, *Erickson v. Pardus*, 551 U.S. 89 (2007); and, exposing uninfected inmates to HCV makes out a separate claim of deliberate indifference to uninfected inmates *Helling v. McKinney*, 509 U.S. 25, 33 (1993). See also *Moore v. Duffy*, 255 F.3d 543 (8th Cir. 2001), *Burke v. N.D. Dept. of Corr.* 294 F.3d 1043 (8th Cir. 2002) (failure to treat HIV/HCV states claim for deliberate indifference to a serious medical need). This exposure to unsafe infectious disease conditions under *Helling v. McKinney*, 509 U.S. 25, 35-37 (1993) (stating claim for second-hand cigarette smoke exposure while Court cites ongoing hepatitis exposure as inherent danger in prison), makes out the *second* of Plaintiffs' major claims.

## F. Hepatitis C: Screening and Treatment At The Minnesota Department of Corrections, ECF106:8-10 -- DISPUTED

### 1. Development of DOC Guidelines for Screening and Treatment of HCV.

It appears that the Parties do not dispute that, sometime *after* Plaintiffs filed their initial Complaint on May 1, 2015 and prior to January 16, 2016 (when the Parties agree the DOC adopted its current protocols, which includes DAA treatment), the DOC eliminated interferon-based HCV treatment and replaced it with DAA therapy as requested in

Plaintiff's Complaint and October 2015 Second Amended Complaint in. (Doc. No. 42).

The relevant dates are as follow:

Oct. 2014 -- FDA: Approval Harvoni/Viekira Pak -- *Interferon* eliminated

Jan. 2015 -- AASLD/IDSA: HCV std-of-care eliminates *Interferon*

*April 2015*[8] *-- DISPUTED: 2015 HCV Guidelines*

April 10, 2015 -- Ligons offered waiver without reference to 2015 Guidelines

May 1, 2015 -- Ligons First Complaint filed.

May/June 2015 -- Answer filed by Defendants without mention of April 2015 Guidelines

June 2015 -- MNDOC supplied to Plaintiffs by Defendants: HCV protocols refer to *Interferon* treatment, no mention of "2015 Guidelines."

June 29, 2015 -- AASLD/IDSA recommends elimination of "prioritization"

Oct. 2015 -- Ligons Second Amended Complaint filed.

Nov. 16, 2015 -- AASLD Liver Meeting Document eliminate "prioritization."

Jan. 4, 2016 -- Scheduling Order limiting amendment of Complaint and adding parties

Jan. 16, 2016 -- MN DOC HCV Treatment Protocols based on "correctional standard of care"

Feb. 2017 -- MN DOC begins treating Ligons for HCV

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[8] Plaintiffs dispute whether the putative 2015 MNDOC HCV Treatment Guidelines were supplied to Plaintiffs when requested at the time the Complaint was filed on May 1, 2015. "Current policy" at that time was described as 2012 Guidelines and treatment described as Interferon-based in June 2015 waiver provided to Plaintiff Ligons. Putative 2015 DOC Guidelines appeared in discovery for the first time in Dr. Paulson's Affidavit, (Paulson Aff. Ex. B), and were not addressed by Dr. Paulson in his deposition, but Mr. Ligons testified that, unlike the purported Guidelines, MCF Faribault officials required CD screening of him first in 2015. Ligons Dep. 79:17-80:23.

Mar. 2017 -- Michaelson released from MN DOC

### a. DOC's April 2015 HCV Treatment Guidelines - DISPUTED

The evidence of "2015 Guidelines" is provided exclusively through a single document provided by Dr. Paulson attached to his own Affidavit, without any evidence it has been circulated to anyone at any time and, particularly, not to Plaintiffs. (Paulson Aff. Ex. B). And, "genuine issues of material fact" do lie if a jury could conclude for Plaintiff based on "all reasonable evidence to be drawn from those facts." *Matsushita*, 475 U.S. at 587.

On 10 April 2015, at the latest, Ligons received a notification form created on March 27, 2015, Paulson Dep. p. 93, Ex. 7, purporting to be the latest information on HCV treatment, including the chemical dependency treatment requirement. Dr. Paulson testified there was no successor to that form, prior to the *January 2016 policy*. In testimony related to Exhibits 10 and 14, one of which is a letter of March 3, 2015, which refers to "new guidelines being reviewed," he testified this was a reference to what became the January 2016 guidelines, *not "2015 guidelines."* Dr. Paulson did not mention the existence of 2015 Guidelines, nor were any produced pursuant to Mr. Nickitas' request for updated information, other than the January 2016 HCV Guidelines, prior to submission of Dr. Paulson's Affidavit.

### b. DOC's January 2016 HCV Treatment Guidelines - DISPUTED

Dr. Paulson's 2016 Guidelines do not meet the AASLD/IDSA medical standard of care. Paulson Aff. ¶56; see also Guidelines at 1; Kendig Rep. at 15-16. As Dr. Kendig stated in his Deposition:

> So, the field of Hepatitis C, I would agree that the Hepatitis C website (http://www.hcvguidelines.org) is the major -- the major for treatment -- is the major source for developing clinical practice guidelines for the correctional setting, but they must be adapted. So to answer your question, are they identical? No. Kendig Dep. p. 22

As pointed out by Plaintiffs' experts in their Reports and Depositions, and as admitted by *both* of Defendants' experts: (a) the medical practitioner standard-of-care is established by the AASLD/IDSA *only*; (b) the AASLD/IDSA standard-of-care requires that all patients presenting with active HCV infections must be treated with DAA drugs to cure the patients; but also to prevent transmission of the virus to uninfected inmates in a prison setting. *Helling v. McKinney,* 509 U.S. 25, 33 (1993).

### 2. Implementation of the DOC's 2016 Guidelines, ECF106:10-11

### a. Screening/b. Monitoring and Treatment DISPUTED

The detailed description of screening that has identified and treated between 10 and 77 of up to 3,500 HCV-positive inmates (estimate according to MNDOC) can be argued as evidence of deliberate indifference. Dr. Paulson states some 77, ECF106:21, HCV-positive inmates are being treated by MNDOC. However, as pointed out earlier, his Deposition claims only 10 inmates have been treated. (Paulson Dep. p. 41), Nanette Larson claims 77 (Larson Aff. ¶14). Universal testing with a possible "opt-out" would be more consistent with the DOC's own estimates. There is no dispute that, under the "prioritization program" the vast-majority of HCV-positive inmates (with Fibrosis scores below F3/F4, F0 to F2, and perhaps over 3,000 individuals) will remain fully infectious as a matter of intentional policy of Dr. Paulson's "prioritization" of treatment. treating only the most damaged liver patients. A material dispute exists whether this procedure meets the

AASLD/IDSA standard-of-care, and thus manifests Eighth Amendment deliberate indifference to the Plaintiffs' serious medical needs of treatment for, and freedom from infection by, HCV.

By waiting for the liver of each patient to deteriorate enough to "earn" being cured of the life-threatening virus, the entire premise of "prioritization," based on non-medical factors being used to deny a medical cure, interferes with Dr. Paulson's dual interests described by the "corrections standard," described by Dr. Kendig as requiring consideration of "resources." Dr. Paulson, himself, directly oversees the deterioration of each liver while the DAA cure is withheld from HCV-positive inmates under his charge....which is all of them.

**G. Cost, ECF106:11-12 -- DISPUTED**

The Parties do not dispute, "correctional systems have a much larger number of patients who are potential candidates for HCV treatment than any other large health care system in the United States." Kendig Rep. at 13. Dr. Kendig acknowledges that "cost is one of the factors" in the correctional standard of care he has proposed. Kendig Dep. pp. 56 *et seq.* (Paulson Aff. Ex. D). In addition, high risk activities in prison settings expose prison inmates to a higher risk of harm than persons not living in a correctional setting. (See, CDC Report on Incarceration, ECF79, Ex. J). Under *Erickson v. Pardus*, 551 U.S. 89 (2007) and *Helling v. McKinney,* 509 U.S. 25, 33 (1993), this means that Defendants have an obligation to a larger number of potential HCV patients than other large health care providers that do not have the responsibility of providing safe living conditions, as do prisons and jails. Even if "staging" did not increase the risk of infection for uninfected inmates, which it does, cost is not a factor in the AASLD/IDSA HCV Guidance Panel

standard-of-care. *http://www.hcvguidance.org*.

Defendants admit setting a $3,000,000 "cap" on the HCV costs that will be paid under the contract with Centurion effective July 1, 2016. (Larson Aff. ¶¶11-12). As of March 6, 2017 the DOC was treating five inmates with DAA, and had treated 77 according to Ms. Larson (Larson Aff. ¶14) out of up to 3500 HCV positive inmates as estimated by DOC, but only ten (10) according to Dr. Paulson. (Paulson Dep. p. 41). A jury could find that setting this "cap" has the effect of making HCV dependent upon the cost that Centurion has agreed to bear. *Matsushita*, 475 U.S. at 587. See *Fields v. Gander,* 734 F.2d 1313 (8th Cir. 1984) (reversing summary judgment in county jail inmate's §1983 action against county sheriff for wrongfully denying inmate dental care because inmate's sworn statement that sheriff knew of his pain for several weeks but denied him dental care in attempt to compel payment of his earlier dental bill raised substantial fact issue as to whether sheriff's conduct violated Eighth Amendment).

ECF93, Dr. Thompson's rebuttal report, makes clear that cost of the HCV medication should have no role in the physician's decision to prescribe, and make out a dispute as to material facts at a minimum. ECF93:

> 27. To the extent that the Federal Bureau of Prisons (FBOP) guidelines state that DAA drugs are the standard-of-care for treating all HCV-positive inmates, with which Dr. Kendig apparently agrees, I have no dispute regarding this as standard of care, i.e. 11. The current FBOP guidelines state the use of DAA therapies is the standard of care for treating inmates with chronic HCV infection.... (Kendig quote, p. 12. para. 3)
>
> 28. Dr. Kendig states that FBOP prioritizing treatment of inmates into categories described on page 13 of his Report are largely due to financial reasons and, as non-medical matters, are beyond my medical expertise. According to Dr. Kendig: "For most state correctional systems and the FBOP

> the immediate treatment of all inmates with HCV infection with the newly available DAA therapies is fiscally unaffordable with existing budgets.... and is of questionable cost effectiveness for inmates with absent or minimal liver disease." (p. 14¶1)
>
> 29. "Affordability" and "cost effectiveness" are not relevant to the medical standard of care for the treatment of HCV or other medical conditions, as far as I am aware. These are not medical considerations in deciding whether to issue a prescription for an HCV positive patient, or not.

See also *Shabazz v. Schofield*, 2016 U.S. Dist. LEXIS 114044 (M.D. Tenn., Aug. 25, 2016) (Hepatitis C-infected inmate demanded AASLD/IDSA standard of care to treat his infection in spite of Tennessee Dep't of Corrections protocol that "monitored" his infection; summary judgment denied to Tennessee Dep't of Corrections).

## H. Plaintiffs' History of Hepatitis C,ECF106:12 -- DISPUTED

References to the medical records of Ligons and Michaelson are incomplete, even with respect to HCV. The Paulson Affidavit denies having knowledge of inmate-to-inmate transmission of HCV. (Paulson Aff. ¶10; Paulson Dep. at 78-81.) Of course, as described in ECF45 and below, both named Plaintiffs only tested HCV-positive after they had been admitted to MNDOC for some years, thus examples of such transmission and present disputed facts.

A.Plaintiffs

1. Ronaldo Ligons

Ronaldo Ligons is an inmate at MCF Faribault. Ligons Dep. 11:19-20. He has been in prison since 1989. Id. at 81:25. He has a scheduled release date in 2019. Id. 10:16-18. He exhausted his administrative remedies. Id., 122:19-22, Defendants' Answers to

Plaintiffs' Requests for Admissions #13-#14 (Defendants not contesting exhaustion by Ligons or Michaelson).

Having never tested positive for HCV before 1998, Ligons Aff. 5/16/2016, ¶10 (first tested positive for HCV in 1998 while in prison, incorporated into Plaintiffs' Answers to Defendants' Interrogatories), he suspects he contracted HCV in prison in 1994-96, at MCF Oak Park Heights (OPH), after a nurse-administered insulin injection with a used needle. Ligons Dep. 14:14-23. He regarded it as "nasty... but I had no choice because I'm totally dependent on the Department of Corrections for all of my medical cares." Id. at 16:5-18.

Ligons has never used IV drugs; never had sex in prison, never had sex with a man, and has been married twice to women. Id. at 66:1-14.

Ligons described physical symptoms attributable to Hepatitis C: panic, fatigue, scabies, joint pains in both elbows, hands, knees, feet, liver area pains, mouth sores that do not heal, sores on his tongue, bumps all over his skin, skin eruptions, and swelling in his feet. Id. a14:5-13, 19:1-25, 30:1-18. Ligons added that he was fighting for his life to be cured of HCV, that he was anxious for seeing men dying in prison from unmet medical needs, he was anxious from dying of HCV, and "scared to death" of dying from liver cancer. Id. at 81:16-25, 82:10-22, 88:7-12. He added that he did not want to wind up like someone in Washington State who had HCV, whose advanced kidney disease because of HCV made him incapable of DAA treatment, and who then died from HCV and kidney failure. Id. at 82:8-15.[9] He suffers from diabetes. Id. at 14:5-14.

[9] See *B.E. v. Teeter*, C16-227-JCC, ECF40, 2016 U.S. Dist. LEXIS 70021, *15-16( W.D. Wash. May 27, 2016) (granting preliminary injunction striking down Washington Medicaid

He described the effect of HCV on interactions with others: he must disclose his disease to cellmates, be careful not to share a razor or a toothbrush, and refrain from sex. He feared fights lest there be HCV-tainted bloodshed. Id. at 38:1-39:8.

Ligons described chronic MNDOC obstacles to his treatment for HCV. One prison doctor, Ceman ("the worst"), told him that Hepatitis C had no effect on mortality. Id. at 24:13-25. Ligons had a biopsy ten years before, with no treatment. Id. at 25:7-21. He described psychiatrist Dr. Paskowitz as indifferent; "You really have a problem, because it's life or death. I'm in a life or death situation and people are acting as if don't care if you live or die." Id. at 29:11-18. He has been billed for separate co-pays for each symptom he reported. Id. at 50:7-17. He obtained interferon treatment in 2006, which failed because of an interruption beyond his control, and false assurances the interruption would not matter, viz. a legal proceeding in Hennepin County. Id. at 22:1-7.

In 2012, he sought HCV treatment with then-new, and now-discontinued medicines, Incivek and Victrellis. He wrote Dr. Paulson, who dismissed him by saying, "We don't treat people based on press releases." Id. at 20:1-12. Dr. Paulson refused to see him at Oak Park Heights ("He was too above talking to me") and Ligons received no HCV treatment. Id., 62:1-24.

Within six months of his February, 2015 transfer to Faribault, Ligons was informed that HCV treatment was conditioned on his undergoing chemical dependency treatment. Id. at

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protocol conditioning HCV treatment with DAAs on fibrosis score; example of male Medicaid recipient and HCV patient dying of kidney failure because of protocol); class cert granted, id., ECF54 (July 21, 2016).

79:17-80:23.[10] He requested a Fibroscan in 2016, yet his caseworker interfered with his request. Id. at 44:10-15.

Ligons likened his treatment for HCV, and compared the 2016 MN DOC protocol to the Tuskegee syphilis experiments:

> It reminds me of -- in fact, I really feel like I am part of a Tuskegee experiment here in Minnesota, in my home state. You know, the Tuskegee experiments were men who had been infected with syphilis, a lot of them black men, some of them were white, but they didn't treat them, they just observed them to see how the disease would progress.... A man who has an investment in his animal is going to get the vet over there to fix it, you know. Their whole attitude is we're just going to watch it and see how it goes. Periodically, they would take a blood test and do a viral load, but nothing about actually curing it, and there's been a cure out for a number of years now. Id. at 26
>
> ...
>
> I just don't get it. I don't get this kind of terroristic stupidity. You know, I can't compare it to a Gestapo, but there's something fundamentally wrong with a society that allows people to come into a place like this where they are totally dependent upon the "caregivers" -- in air quotes I said -- and they have no option outside of this place and they refuse to cure diseases. They sit back like a Tuskegee experiment and just say, Okay, we'll see when the syphilis kills this guy or what lesions he develops or what mental health problems he goes through. Does he blow his stack? Well, we got something for that. Id. at 79-80.
>
> ...
>
> Q: Have you read the current Hepatitis C protocol from the Department of Corrections?
> A: Yeah. It's a crock.... The protocol is, from what I recall, is to treat people three and four -- the Tuskegee experiment again -- and not one and two. Last I found out, I was a two and that was, what, 2002? It's been a long time, let's put it that way.
> Q: After the liver biopsy?
> A: That's -- yeah, the liver biopsy, whatever year that was, and I don't -- I'm afraid. Id. at 111:7-21.

Ligons met with Dr. Thompson for approximately two hours in 2016. She prescribed

[10] In contravention of the AASLD/IDSA and in contradiction of Paulson's purported MN DOC 2015 protocol.

Harvoni for him, approximately three weeks before his deposition. Id. at 112:1-20. MN DOC began to treat Ligons with Zepatier on or about 27 February 2017, nearly three months later, and four days after the issuance of the amended briefing schedule, ECF98.

Ligons wants to go forward with his case, whether he is treated or not. Id. at 116:9-10 ("Because people are – I could get this stuff again[]"). He wants testing, and retesting of MN DOC for HCV, to stop unknowing spread. Id. at 116-118, quoting 116:20-25:

> [T]oo many damn people come through prison with this disease for it to be let loose back on the public. It's just unconscionable for the State of Minnesota and the people running the Department of Corrections to let another Tuskegee experiment go on and loose it on the nation, including me.

2. Barry Michaelson

Barry Michaelson has Hepatitis C. Mr. Michaelson was in DOC custody from 2008 to 27 March 2017. He had a medical assessment during processing at MCF St. Cloud in 2009. Michaelson Dep. 23:15-24:5. He tested negative for HCV at that time. Ligons-Michaelson Answers to Defendants' Interrogatories #13.

As an inmate at MCF Stillwater in July-August, 2010, he was forced by a guard to clean up the blood spill of his HCV-infected cellmate, D_____ a man known to MNDOC to be HCV positive[11], while clad in boxer shorts, T-shirt, and bare feet, and issued paper towels, without any protective clothing or standard cleaning materials. Michaelson Dep. 43:9-25.

He demanded HCV testing. Michaelson Dep. 43:1-24. In October 2010, he found

[11] Declaration of Peter J. Nickitas, MNDOC0001-0005-Ex.M (D_____ medical records; 2009 MN DOC record showing him to be HCV positive), under seal.

out from Dr. Quanbeck, a prison doctor, he tested positive for HCV. Id., 42:1-12.

He submitted a "kite" request for HCV treatment. Declaration of Peter J. Nickitas, declared kite of Barry Michaelson. He exhausted with final denial by Nanette Larson in 2012. Id., 42:13-16. He kited again for HCV treatment in 2015, "when Sovaldi came around." Id., 42:17. Defendants do not deny that he exhausted his administrative remedies. Defendants' Answers to Plaintiffs' Requests for Admissions #13-#14, supra.

Mr. Michaelson engaged in none of the usually suspected HCV-risk conduct – tattoos, intravenous drug use, or multiple sexual partners. He was a blood and plasma donor, id., 44:1-45:25, and received outpatient treatment for marijuana, alcohol, and cocaine abuse. Id. at 111:13-17.

Mr. Michaelson's HCV physical symptoms include waxing and waning rashes, itching, erupting 1/16" pustules where the rashes present and bleeding where itched, quarter-sized scarred elbow from itching, 6" x 1.5" scarring on left shin from itching, scaling after the itching eczema, joint pain in the wrists, elbows, shoulders, knees, and ankles, headaches, pain in heels, severe dry eye, detected fat infiltration of the liver from an echogenic ultrasound of the liver, sun-sensitive rash, hand numbness, and diminished energy. Id. at 47-60, 61:15-16 (describing 1/16" pustules), 63:3-4 (describing phantom pain), 63:11-64-15 (heel pain and knee pain two days before deposition), 84:14 (sun-sensitive rash), 83:22 (confirming phantom symptoms after meeting with Dr. Thompson). His psychological symptoms include depression from having HCV, id. at 88:2-4, and depression from HCV being ignored by DOC. Id. at 89-91. He received a prescription for Harvoni from Dr. Thompson, but the Defendants refused to fill it. Id., 100:7-8, 152:21-153:3.

Mr. Michaelson identified by name one inmate who died from HCV, two infected inmates who were released, and five current inmates with HCV. Id. at 137-143.

As to relief in the case, Mr. Michaelson stated the case was about the standard of care. Id., 148:15-19. Mr. Michaelson wants treatment for himself, treatment for others, id. at 147:14-19, testing for HCV as DOC tests for HIV, 148:1-7 (start with prison, to keep from spreading HCV around nation), 155:11-25, class representative remedies are secondary, id. at 133:11-13, and "let the jury decide damages," at 132:12-17.

3. Lawrence Maxcy

Lawrence Maxcy is a current inmate of MNDOC with the HCV infection. He exhausted his administrative remedies in 2015.

4. Devon Farley

Devon Farley is a current MCF Faribault inmate with the HCV infection. He exhausted his administrative remedies with the denial of his demand for DAA treatment of HCV by Health Services Director Nanette Larson in March 2017. Nickitas Decl., Kite and Grievance of Devon Farley.

## II. UNDISPUTED FACTS SUPPORT SUMMARY JUDGMENT ON PLAINTIFFS' CLAIMS OF DELIBERATE INDIFFERENCE TO: (A) CURING HCV USING THE AASLD/IDSA STANDARD OF CARE, AND (B) EXPOSING UNINFECTED INMATES TO HCV

In October 2013, with FDA approval of direct-acting anti-viral (DAA) drugs *Sovaldi* (sofobusivir) and *Olysio* (simeprevir) the highly infectious, formerly incurable and deadly

HCV became predictably curable at a 90-95% cure rate for the first time.[12] In October of 2014 the FDA approved Harvoni and Viekira-Pak; in January 2016 Zepatier was approved and in July 2016, Epclusa received FDA approval. These DAA drugs all provide a sustained viral response (SVR) "cure" to HCV in approximately 8-12-weeks of daily oral medication, and prevent transmission of the virus to others.[13]

Beginning in January 2014, the American Association for the Study of Liver Disease (AASLD), the Infectious Disease Society of America (IDSA), and the International Anti-viral Society-US (IAS-US) formed the AASLD/IDSA/IAS-US HCV Guidance Panel and established the *http://www.hcvguidlines.org* website to publish up-to-date research findings and treatment recommendations for HCV treatment practitioners.

The AASLD/IDSA is acknowledged as source for the HCV standard of care by the Centers for Disease Control and Prevention (CDC); the Federal Bureau of Prisons (FBOP); the Veterans Administration (VA); Plaintiff's experts, Dr. Julie Thompson, ECF79, ECF93; Dr. Bennett Cecil, ECF36; Dr. Martin Gordon, ECF37; Defendant Dr. David Paulson and proposed Defendant's expert Dr. Newton Kendig:

> The AASLD (American Association for the Study of Liver Disease and IDSA (Infectious Disease Society of America) recommend that nearly all persons with chronic HCV infection be considered candidates for treatment with DAAs due to the multiple patient benefits and public health advancements associated with curing HCV infection." Kendig Report p. 8¶4.

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[12] The HCV website is provided by the American Association for the Study of Liver Disease and the Infectious Disease Society of America (AASLD/IDSA) in collaboration with the International Anti-viral Society-USA (IAS-USA), *http://www.hcvguidelines.org*

[13] Id.

The AASLD issued the following statement on November 16, 2015 during the annual AASLD Liver Meeting®, of some 10,000 of the leading liver specialists in the world:

> ***AASLD: Leading Liver Doctors: Hepatitis-C Patients Must Be Treated***
>
> Over the past two-plus years, the Food and Drug Administration has approved multiple new treatments for hepatitis C virus (HCV) that offer nearly universal cure rates with minimal side effects. It is a remarkable success story for medical science. Unfortunately, many insurers – both private and public – are delaying access to new HCV treatments to patients until their disease has progressed and the liver is further damaged. There is no medical evidence to justify that position and much to justify treating all patients.
>
> **AASLD endorses treating patients with HCV as the standard of care.** In the regularly revised HCV Practice Guidance of the AASLD and Infectious Disease Society of America we recommend the early treatment of chronic HCV infection before the development of sever liver disease and other complications to improve overall survival rates. Studies demonstrate that new treatments cure more than 99 percent of patients followed for five years.
>
> **HCV treatment that leads to a cure is the only evidence-based intervention to prevent liver disease progression.** A significant proportion of people living with HCV who have no or mild fibrosis (commonly described as F0-F2) will progress to cirrhosis in the absence of treatment. Currently, there is no way to predict who will develop advanced liver disease.
>
> **Inaction is harmful to patients.** Untreated HCV has been linked to many causes of death, such as liver cancer and kidney problems. Delaying treatment for patients until they develop advanced liver disease leads to higher costs and higher demand for liver transplants. Patients who are unable to obtain curative treatment are at high risk for anxiety, illness uncertainty (the inability to determine the meaning of illness-related events), and depression, regardless of fibrosis stage. Patients who are cured of HCV report a significant improvement in their mental well-being.
>
> **Failure to treat leads to other medical problems.** Among them are HCV-associated heart disease, lymphatic cancers, particularly non–Hodgkin Lymphoma, kidney damage in many patients and evidence of immune related disease when tested for rheumatoid factors. Studies show that HCV infection increases the risk of insulin resistance and diabetes by almost four times. Diabetes increases the risk of liver cancer in people living with HCV.
>
> **Access to curative therapies is the most effective way to eliminate the virus at a population level.** The Department of Health

> and Human Services has cited an "emerging epidemic of HCV infection among young persons who inject drugs." Providing treatment to injection drug users is crucial to reducing the HCV burden within networks and preventing new transmissions. In addition, curing HCV is the best way to guarantee that women of childbearing potential do not transmit the virus to their developing fetus if they become pregnant. *http://hivandhepatitis.com/hcv-policy-advocacy-2015-liver-doctors-and-advocates-call-for-wider-treatment-of-people-with-hepatitis-c.*

A low fibrosis score does not necessarily correlate with minor liver damage. According to the AALS/IDSA Guidance Panel statement of July 8, 2016:

> Fibrosis progression varies markedly between individuals based on host, environmental, and viral factors. (Feld, 2006) Fibrosis may not progress linearly. Some individuals (often those aged >50 years) may progress slowly for many years followed by an acceleration of fibrosis progression. Others may never develop substantial liver fibrosis despite longstanding infection. The presence of existing fibrosis is a strong risk factor for future fibrosis progression. Fibrosis results from chronic hepatic necroinflammation, and thus a higher activity grade on liver biopsy and higher serum transaminase values are associated with more rapid fibrosis progression. (Ghany, 2003) However, even patients with normal ALT levels may develop substantial liver fibrosis over time. (Pradat, 2002); (Nutt, 2000). The limitations of transient elastography and liver biopsy in ascertaining the progression of fibrosis must be recognized. *http://hcvguidance.org/.* (emphasis added)

The Minnesota DOC protocols that deny HCV treatment to patients with fibrosis levels below F3 and F4 by definition, deny treatment to the majority of HCV patients who have with fibrosis levels F0 to F2 that the HCV Guidance Panel specifically identifies as requiring treatment, and who are as infectious to others as those with higher FIB levels.

The AASLD/IDSA HCV Guidance Panel explicitly recommends DAA drugs for all HCV positive patients *without* prioritization because of deterioration of the liver:

> Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure, and as such, is expected to benefit nearly all chronically infected persons. When the US Food and Drug

> Administration (FDA) approved the first IFN-sparing treatment for HCV infection, many patients who had previously been "warehoused" sought treatment, and the infrastructure (experienced practitioners, budgeted health-care dollars, etc) did not yet exist to treat all patients immediately. Thus, the panel offered guidance for prioritizing treatment first to those with the greatest need. Since that time, there have been opportunities to treat many of the highest-risk patients and to accumulate real-world experience of the tolerability and safety of newer HCV medications. More importantly, from a medical standpoint, data continue to accumulate that demonstrate the many benefits, within the liver and extrahepatic, that accompany HCV eradication. Therefore, the panel continues to recommend treatment for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Accordingly, prioritization tables are now less useful and have been removed from this section.[14] (emphasis added)

Both proposed Defense expert Dr. Kendig and Dr. Paulson acknowledged that the current AASLD/IDSA standard of care is to treat "nearly-all" actively HCV-infected patients with the DAA drugs to cure the HCV infection, and prevent infecting others, irrespective of the level of the active HCV infection detected in the patient, or the fibrosis level of the liver.

However, the January 2016 MNDOC guidelines do *not*: (a) comply with the AASLD/IDSA standard of care to treat "nearly all persons with chronic HCV infections," the vast majority of whom are below fibrosis scores F3 and F4 (i.e. F0 to F2), as Dr. Kendig's Report and Dr. Paulson's Affidavit admit; (b) screen *all* incoming inmates to determine which new inmates are HCV-positive; (c) provide regular screening for inmates who may become infected during their incarceration; (d) protect uninfected and cured inmates from infection or re-infection by HCV-positive inmates at large in the general

[14] "When and in Whom to Initiate HCV Therapy" AASLD/IDSA HCV Guidelines, July 6, 2016. *www.hcvguidelines.org* (accessed November 18, 2016) (emphasis added).

population; and (e) prevent HCV-positive inmates from being released into the general population to infect others.[15]

## III. THE KENDIG REPORT AND TESTIMONY ARE SUBJECT TO EXCLUSION UNDER *DAUBERT V. MERRELL DOW,* 509 U.S. 579 (1993).

Dr. Kendig agrees with Plaintiffs' experts: the liver and infectious disease *medical community* standard-of-care for the treatment of the potentially fatal Hepatitis-C virus (HCV) is established by AASLD/IDSA Guidance Panel (*http://hcvguidelines.org*), *NOT government agencies or prisons. Further,* the AASLD/IDSA standard-of care requires treatment of "nearly all" HCV-positive patients with direct-acting anti-viral (DAA) drugs that cure the HCVand prevent the spread of infection to others irrespective of the level of liver fibrosis:

> "The AASLD (American Association for the Study of Liver Disease and IDSA (Infectious Disease Society of America) recommend that nearly all persons with chronic HCV infection be considered candidates for treatment with DAAs due to the multiple patient benefits and public health advancements associated with curing HCV infection." Kendig Report, p.8¶4.

Plaintiffs' experts, Dr. Julie Thompson MD of the University of Minnesota, ECF79, ECF93 and Dep. pp. 101-02, 112; Dr. Bennet Cecil MD of Louisville, KY, ECF36 and Dep. 48:1-25 (HCV as disabling from mental anguish arising from "1 in 3 chance of dying from a curable disease"), 100:10-20 (protocol limiting HCV treatment to F3 and F4 not consistent with standard of care); and Dr. Martin Gordon MD of St. Louis, MO, ECF37

[15] Please refer to Memorandum Opinion, (Ex. A, attached) *Abu-Jamal v. Kerestes, No.* 3:13:cv-967 (M.D. Pa. Jan. 10, 2017)

and Dep. 51-52, 59-60, and 72-73 confirm the AASLD/IDSA HCV Guidance Panel Guidelines, http://www. hcvguidelines.org, provide the standard-of-care for the treatment of HCV-positive patients.

Dr. Kendig and Dr. David Paulson, the Minnesota Department of Corrections (MNDOC) Medical Director, do not dispute: (a) the AASLD/IDSA HCV Guidance Panel (*http://hcvguidelines.org*) is the source of the accepted medical standard-of-care (See generally. Kendig Report. p. 8); and, (b) the AASLD/IDSA standard-of-care is to treat "nearly all" HCV-positive patients with direct-acting anti-viral drugs to: (a) cure HCV-positive patients, irrespective of fibrosis level and (b) prevent the spread of HCV to uninfected persons. (*http://www.hcvguidelines.org*) Dr. Kendig admits he would not treat his private patients with the "corrections" standard-of-care he advocates for prisoner-patients:

> Q. Would you use the correctional standard of care for treating Hepatitis C patients in a private clinical setting in 2016.
>
> *A. NO.* Kendig Dep. p.25 (emphasis added)

The vast majority of HCV-positive MNDOC inmates remained unscreened for HCV, untreated, uncured and infectious. Waiting for an infectious disease to further progress in possibly irreversible destruction of liver cells, before permitting the infection to be cured with readily available safe medication, is the very definition of "deliberate indifference" to the disease process, itself, as well as the danger of transmission of a potentially fatal virus to others.

### A. The Non-medical, Non-Scientific "Correctional Standard of Health Care"

Although Dr. Kendig acknowledges AASLD/IDSA standard-of-care requires prescribing DAA curative drugs to "nearly all" HCV positive patients, as he must, he asserts a separate "correctional standard-of-care" that applies only to prison imates, to wit:

> I am assigned by the Minnesota Department of Corrections (MNDOC) to provide expert witness services for the State in the case of Ronaldo Ligons *et al* v. Minnesota Dept of Corrections et al. My assignment includes the review of the Minnesota Department of Corrections Guidelines for the Evaluation and Treatment of Chronic Hepatitis C (HCV) Infection (January 2016), and related background materials, to determine if these guidelines are consistent with the correctional standard of care for the management of inmates with chronic HCV infections in 2016. (*Kendig Report*, p. 1)

According to Dr. Kendig's *Summary of Conclusions (Kendig Report p. 5),* rather than applying the AASLD/IDSA HCV medical community standard of care, which he admits would be applicable to his private patients in 2016 (see above), Dr. Kendig asks the Court to accept his own "population-based," "correctional standard-of-care" to evaluate the lower HCV treatment protocols of MNDOC:

> [T]*he correctional standard of care* for treating inmates with chronic HCV infection in 2016 is to prioritize treatment with the newly available curative DAA therapies for inmates who have the more advanced liver disease (METAVIR F3-F4). This prioritization approach is warranted in the correctional setting due to *the enormous number of inmates who have chronic HCV infection; the associated logistical and security challenges* for immediately treating all inmates with HCV; *the questionable cost effectiveness* of immediately treating persons with HCV who have no or minimal liver disease; *the very high costs for DAA therapies* that makes immediate treatment of all inmates with DAA with HCV infection unaffordable; and the inherent population approach to correctional medicine that that requires the health care *system to appropriately allocate and*

> *prioritize medical care to inmate-patients* based on the urgency of their individual health care needs
> ....The Minnesota DOC guidelines for treating inmates with chronic HCV infection are *medically appropriate,* consistent with the correctional standard of health care, and not deliberately indifferent to the serious medical needs of inmates *generally*. (emphasis added) Kendig Report*, p.5*.

The proposed "correctional standard of HCV care" is designed to delay treatment of the vast majority of HCV-positive inmate-patients, F0 to F2, until their liver fibrosis levels deteriorate to the most serious levels of liver disease, F3 or F4 on the fibrosis scale). Dr. Kendig purports to justify "gradually treating inmates based on disease severity using the financial resources and costs as a rationale for denial and delay (see Report, p 5 above), and summary below. Id., p. 13:

> (1) correctional systems have a large number of HCVpatients; (*undisputed*)
>
> (2) the HCV treatment logistics are daunting, which will require expenditure of resources; (i.e. *financially-based*)
>
> (3) the fiscal burden dwarfs previous fiscal burdens; (i.e. *financially-based*)
>
> (4) correctional health administrators operate within fixed budgets; delaying HCV treatment is cost-effective; (i.e. *financially-based*)
>
> (5) correctional health care providers practice population medicine; not community-based care. (*irrelevant with respect to treatment of each individual seeking treatment.*)

## B. The Legal Opinion by Dr. Kendig, MD and *Estelle*.

The Kendig Report, pp.10-11, provides the source of the "correctional standard-of-care" about which Dr. Kendig opines, he states that "Estelle v. Gamble" (without citation):

> ...does not require that correctional authorities provide any type of care that an inmate may request. *Correctional authorities must thus determine an appropriate standard of medical care for the correctional context.* Id.:10.

As the Court knows, the holding of *Estelle v. Gamble* 429 U. S. 97 (1976) establishes that:

> ... In order to state a cognizable claim, a prisoner must allege acts or omissions sufficiently harmful to evidence deliberate indifference to serious medical needs.... Id. at 106

The Court would be justified in excluding the incorrect and misleading discussion in the remainder of the Report on this misstatement of the legal standards applicable to evaluating Eighth Amendment requirements alone. *See In re Acceptance Ins. Cos. Sec. Litig.*, 423 F.3d 899, 905 (8th Cir. 2005) (affirming exclusion of expert opinions that were "more or less legal conclusions about the facts of the case . . . meant to substitute the judgment of the district court").

On its face, the Kendig Report contemplates *no role* for: (a) the Eighth Amendment "deliberate indifference" to the treatment of each individual patient-inmate, established by *Estelle v. Gamble* 429 U. S. 97, 106 (1976); (b) other opinions of the Supreme Court, which hold a prison officials liable who know of, and disregard, "*excessive* risk*," Farmer v. Brennan*, 511 U.S. 825, 837 (1994); or (c) "*future* harm" to inmate health *Helling v. McKinney*, 509 U.S. at 33-37 (with specific mention of hepatitis); or (d) the medical community standards-of-care which makes it possible to distinguish mere medical negligence from deliberate indifference. *U.S. v. Kubrick*, 444 U.S. 111, 123 (1979). In the Eighth Circuit, the standard was clearly established before *Jolly v. Knudson*, 205 F.3d at 1095:

> Our court has interpreted this standard as including both an objective and a subjective component: "The [plaintiff] must demonstrate (1) that [he] suffered [from] objectively serious medical needs and (2) that the prison officials actually knew of but deliberately disregarded those needs." *Dulany v. Carnahan,* 132 F.3d 1234, 1239 (8th Cir.1997).

The *intentional* replacement of the medical community standard of care with proposed non-medical, "correctional health care standards of care" (1) admits deliberate indifference to a serious medical needs by intentionally delaying curative treatment, and (2) does not meet the standard for expert testimony required under the *Daubert/Kumho Tire* test. See *Unrein v. Timesavers, Inc.* 394 F.3d 1008, 1011 (8th Cir. 2005) (expert exclusion aff'd).

**C. Defendants Contractually Admit the "Medical Community Standard of Care" Applies within MNDOC Facilities.**

Defendants have already acknowledged that the medical community standard of care must be provided to prisoners with HIV/AIDS, as reflected the current Contract #70449 between the Minnesota Department of Corrections (MNDOC) and private medical care contractor (Centurion of Minnesota). HCV treatment is a contractual exception. ECF93, Contract terms Section I, infra:

Defendants acknowledge the treatment of HIV/AIDS must be "in a manner consistent with applicable standards of medical care, including CDC guidelines and the Twin Cities area community standard of care...." thus admitting their mutual obligation to provide medical care at a level beyond the self-referential "correctional standard of care" to which Dr. Kendig's Report is directed, and the contract permits, for HCV treatment by exception to *Estelle*, supra. However, Dr. Kendig admits that the AASLD/IDSA is the source for HCV clinical practice guidelines, even in prisons:

> So, for the field of Hepatitis C, I would agree that the Hepatitis C website http://www.hcvguidelines.org is the major -- the major -- for treatment -- is the major source for developing clinical practice guidelines for the correctional setting, but they must be adapted. So the answer to your question, are they identical? No. Kendig Dep. p. 22.

## D. The Kendig Report Fails the Daubert /Kumho Tire Test

In response to the question in a Deposition on March 11, 2016, "would you use the correctional standard-of-care for treating Hepatitis C patients in a private care setting in 2016," Dr. Kendig replied "No." Dr. Kendig's Report is directed to (an) issue(s) not before the Court and misstates the legal principle at issue of *Estelle* and its progeny. Under Estelle the only questions before the Court are" in the medical-standard-of-care context:"

> ... *Similarly, in the medical context,* an inadvertent failure to provide adequate medical care cannot be said to constitute "an unnecessary and wanton infliction of pain" or to be "repugnant to the conscience of mankind." Thus, a complaint that a physician has been negligent in diagnosing or treating a medical condition does not state a valid claim of medical mistreatment under the Eighth Amendment. Medical malpractice does not become a constitutional violation merely because the victim is a prisoner. In order to state a cognizable claim, a prisoner must allege acts or omissions sufficiently harmful to evidence deliberate indifference to serious medical needs.... *Estelle,* 429 U.S. at 106.

Defendants admit their decision not to adhere to the HCV medical community standard of care was conscious and intentional. Fed. R. Evid. 702 requires that the expert testimony be relevant, that the witness be qualified regarding the subject matter of the testimony, and that the evidence be reliable. Additionally, Fed. R. Evid. 403 provides that evidence may be excluded if its "probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury..." Under *Daubert*:

> ... the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. The primary locus of this obligation is Rule 702, which clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify. "*If scientific*, technical, or other specialized *knowledge will assist the trier of fact* to

> understand the evidence or to determine a fact in issue" an expert "may testify *thereto*." The subject of an expert's testimony must be "scientific . . . knowledge." The adjective "scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Webster's Third New International Dictionary 1252 (1986).... in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation--*i.e.*, "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

*Daubert*, 509 U.S. at 590.

As compared with the AASLD/IDSA "medical community standard of care" the *sui generis* Kendig "correctional standard of care" is not reliable specialized knowledge that will aid the trier of facts to understand either: (a) the serious medical need to treat HCV infection, nor (b) the deliberate indifference to the medical community standard of care HCV that delay in treating the virus creates as a matter of medical practice, at issue in this matter. In fact, the "correctional standard of care" introduces non-medical, financial, resource and non-patient-specific considerations that the Supreme Court has specifically prohibited from consideration regarding the medical standard of care.

"[T]he plaintiff must establish a mental state akin to criminal recklessness: disregarding a known risk to the inmate's health." *McCaster v. Clausen,* 684 F.3d 740, 746-747 (8th Cir. 2012). There is a question of material fact when " ... medical treatment may so deviate from the applicable standard of care as to evidence a physician's deliberate indifference, *see Smith v. Jenkins,* 919 F.2d 90, 93 (8th Cir. 1990), often requiring expert opinion to

resolve..." *Moore v. Duffy*, 255 F.3d 543, 545 (8th Cir. 2001) (denial of qualified immunity in failure to treat prisoner's HIV/HCV).

The "correctional standard of care" proposed by Dr. Kendig contravenes the AASLD/IDSA medical community standard of care by "intentionally denying and delaying access" to the DAA medications that cure HCV infections. Dr. Kendig agrees the standard of care established by AASLD/IDSA applies to patients who are not prisoners, yet proposes a "correctional standard of care" that is neither scientific, nor supported by the HCV medical treatment community, nor supported in law. *Kumho Tire v. Carmichael*, 526 US 137 (1999).

## E. The "Correctional Standard of Health Care" is Scientifically Unreliable and Prejudicial under the Daubert/Kumho Tire Standards.

Expert testimony should be excluded when it is "so fundamentally unsupported that it can offer no assistance to the jury." *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004), *Unrein v. Timesavers, Inc.* 394 F.3d at 1010-11. The "*correctional* standard of care," which includes cost and resource factors *unrelated to the medical community standard-of-care established by the AASLD/IDSA* is without probative value re: medical standard-of-care and is highly prejudicial, particularly when cost is not a defense to the failure of a State to provide necessary medical care, or other constitutionally required services. See, *Watson v. City of Memphis*, 373 U.S. 526, 537 (1963); *Wright v. Rushen*, 642 F.2d 1129, 1134 (9th Cir. 1981); *LaMarca v. Turner*, 995 F.2d 1526, 1536–39, (11th Cir. 1993), *Barron v. Keohane*, 216 F.3d 692 (8th Cir. 2000). It is evidence that is not

relevant, material or reliable in responding to expert testimony establishing the medical community standard-of-care.

In *Kumho Tire v. Carmichael*, 526 US 137, 153 (1999), the district court did not question the expert's qualifications, but excluded his testimony because it found his methodology unreliable, as should this Court with respect to Dr. Kendig on the question of the "medical community standard-of-care" vs. the *sui generis*, self-referential "correctional standard of care." Dr. Kendig's methodology cannot reliably determine any of the issues in this case without reliance on the AASLD/IDSA medical community standard of care. Dr. Kendig's Report fails to provide reliable, scientific evidence on any relevant factual issue that is properly before the fact-finder in this case. The "correctional standard of care" is not properly a subject for expert testimony under the *Daubert/Kumho Tire* test.

## F. Deliberate Indifference as a Jury Issue

While the Eighth Circuit has held that expert opinion on the ultimate jury question permissible, *U.S. v. Two Eagle,* 318 F.3d 785, 792-93 (8th Cir. 2003), "deliberate indifference" is of particular concern. See *Bruner-McMahon v. Sedgwick Cnty. Bd. of Comm'rs*, 10-cv-1064, 2012 WL 33837, *6 (D. Kans. Jan. 6, 2012). ("[E]xperts may not testify that someone was `deliberately indifferent,' because that is a legal conclusion reserved for the trier of fact based upon the facts provided at trial and the law provided by the court.")

While the Eighth Circuit in *Two Eagle* provided that use of legal phrases with overlapping meanings in everyday parlance are permissible (e.g., "serious medical need"), chambers of this U.S. District Court have held that "deliberate indifference" is nonetheless

problematic because it is a legal phrase that contemplates criteria that has potential to confuse a jury.

> .... unlike "serious medical need," "deliberate indifference" does not simply mean what plain language might suggest (e.g., that someone purposefully behaved in a careless manner). Rather, the phrase has a more nuanced meaning, describing an actor's decision to consciously disregard a serious medical need in the manner and to the extent contemplated by various cases. Additionally, the policy considerations explored in *Two Eagle*—that medical experts should not be precluded from using the terms of their field— does not apply here; "deliberate indifference" is not known to be medical term of art. Therefore, while *Two Eagle* applies, its application is somewhat limited here. Accordingly, the Court concludes that the phrase "deliberate indifference" has a plain meaning that does not encompass its legal meaning...

*Mace v. Johnson*, 11-cv-0477 (D. Minn. Jan. 10, 2014) MJD/LIB.

The same analysis should apply to "medically appropriate," "consistent with the correctional standard of health care," and "not deliberately indifferent to the serious medical needs of inmates generally." Kendig Report, p. 5. None of the medical experts dispute that current AASLD/IDSA Guidelines provide the HCV medical community standard-of-care, and that under that standard nearly all HCV positive patients should be cured with the new DAA drugs.

Dr. Kendig's Report fails to apply the AASLD/IDSA medical community standard-of-care for HCV prescribing practitioners. Dr. Kendig's report is without scientific medical basis and is not relevant to any issue properly before this Court under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and *Kumho Tire v. Carmichael*, 526 US 137 (1999). The Court must exclude Dr. Kendig's report, and strike it from consideration of the Defendants' Rule 56 motion.

## IV. STANDARDS FOR INJUNCTIVE RELIEF

When deciding a motion for a preliminary injunction, the Court should consider: (1) the moving party's probability of success on the merits; (2) the threat of irreparable harm to the moving party; (3) the balance between this harm and the injury that granting the injunction will inflict on other interested parties; and (4) the public interest in the issuance of the injunction. *Dataphase Sys., Inc. v. C L Sys., Inc.,* 640 F.2d 109, 114 (8th Cir. 1981) (en banc)....Although "no single factor is determinative," the probability-of-success is the most significant. *Sharpe v. U.S. Dep't of Health and Human Svcs.,* 801 F. 3d 927 (8th Cir 2015).

### A. Probability of Success on the Merits

To prevail on a claim for claim for deliberate indifference, Plaintiffs must show that he was suffering from an objectively serious medical need, and that prison officials knew of the need but deliberately disregarded it, as Defendants did with the DAA cure for HCV. *See Saylor v. Nebraska*, 812 F.3d 637, 643–44 (8th Cir. 2016).

#### 1. *HCV is a Serious Medical Need for Those Infected, AND Potential Serious Harm To Others.*

The Supreme Court has long recognized that infection with the Hepatitis-C virus (HCV) is a serious medical need, *Erickson v. Pardus*, 551 U.S. 89, 91-92 (2007), and, *exposing* uninfected inmates to HCV makes out a claim of deliberate indifference, as the Court *specifically* mentioned *Helling v. McKinney*, 509 U.S. 25, 33 (1993). See also,

*Moore v. Duffy,* 255 F.3d 543 (8th Cir. 2001), *Burke v. N.D. Dept. of Corr.* 294 F.3d 1043 (8th Cir. 2002) (failure to treat HIV/HCV states claim for deliberate indifference to a serious medical need).

The AASLD/IDSA lists "incarceration" as a main HCV risk-factor, *standing alone*, because of the large percentage of inmates who are HCV-positive and the conduct in prison that makes exposure more likely. There is no dispute that *both* Ligons and Michaelson were infected after being incarcerated in the DOC. This confirms inmate-to-inmate transmission does occur despite Dr. Paulson's stated opinion to the contrary. Paulson Aff. ¶10.

### 2. Failure to Cure Each HCV-Positive Inmate with the AASLD/IDSA Standard of Care, and Allowing the Inmate to "Deteriorate Under Observation," Admits Deliberate Indifference to Worsening Physical Condition, as a Matter of Policy.

To show that a defendant knew of but deliberately disregarded an objectively serious medical need, or *harm*, "the plaintiff must establish a mental state akin to criminal recklessness: disregarding a known risk to the inmate's health." *McCaster v. Clausen*, 684 F.3d 740, 746-747 (8th Cir. 2012). There is a question of material fact, " ... medical treatment may so deviate from the applicable standard of care as to evidence a physician's deliberate indifference, *see Smith v. Jenkins,* 919 F.2d 90, 93 (8th Cir.1990). Whether such a significant departure from professional standards occurred is a factual question "...requiring expert opinion to resolve..." *Moore v. Duffy*, 255 F.3d 543, 545 (8th Cir. 2001) (denial of qualified immunity in failure to treat prisoner's HIV/HCV).

This is a requirement with which Plaintiffs have complied through the reports of three expert witnesses familiar with the AASLD/IDSA standard-of-care for the treatment of HCV. See ECF79, ECF93, ECF36, and ECF37 – a point not disputed by Dr. Kendig or Dr. Paulson *outside* the "correctional context." (Kendig Dep. pp. 22, 25)

This factual question can *only* be resolved based on expert testimony regarding the medical community standards of care, *Kubrick*, 444 U.S. at 123, not self-referential "made-to-fit" standards applicable only *within* particular correctional institutions. Defendants may only rebut with expert testimony contesting, as in this case, that treatment for HCV-positive patients with the new DAA curative drugs IS, or IS NOT, the medical community standard of care for the serious medical need at issue. See *Unrein v. Timesavers, Inc.* 394 F.3d 1008 (8th Cir. 2005). But Defendants admitted that the AASLD/IDSA sets out the HCV medical community standard of care. That which defeats the Defendants on summary judgment forecasts victory for the Plaintiffs on the merits.

### 3. Refusal to Adopt the HCV Medical Standard-of- Care is Not a Mere Disagreement with the Course of Care.

The issue before the Court is not simple medical malpractice or "an inadvertent failure to provide adequate medical care." *Estelle,* 429 U.S. at 105. Plaintiffs have shown that Defendants have deliberately denied providing treatment to inmates with a serious medical condition and chosen a course of nontreating monitoring instead. They have done so with the knowledge that (1) the standard of care is to administer DAA medications irrespective of the stage of liver fibrosis; (2) inmates are likely suffer from hepatitis C complications and disease progress without curing the viral infection; and (3) the delay in receiving curative

DAA medications reduces their efficacy. See *Abu-Jamal v. Wetzel, et al.*, 16-cv-2000 (M.D. Pa. Jan. 3, 2017) describing *all* "prioritization protocols":

> The new protocol implemented by the DOC is also a prioritization protocol because it classifies inmates into different priority levels for treatment, (Doc. 18-1 at 7-8). Much like the interim protocol, however, the new protocol completely bars those with chronic hepatitis C but without vast fibrosis or cirrhosis from receiving DAA medications. Upon review by the Committee, if an inmate is considered for treatment with DAA medications, the Committee orders shear wave elastography to determine the inmate's fibrosis level. *[Id.* at 10). Upon the results of that test, if the inmate has a fibrosis level of F0, F1, or F2, the protocol instructs the Committee to order monitoring but not treatment with DAA medications. (*Id.* at 11). Thus, those with mild or moderate fibrosis have no chance of receiving DAA medications—the standard of care—and the protocol requires their hepatitis C to worsen before they will be considered for treatment.
>
> In addition, the policy does not ensure that those with vast fibrosis or cirrhosis—and who do not have any contraindications—will definitely receive DAA medications. Instead, the Hepatitis C Treatment Committee must still recommend treatment with DAA medications after determining whether the inmate meets "current priority criteria for greatest need of treatment." (Doc. 18-1 at 11).

Dr. Kendig agrees the standard of care established by AASLD/IDSA applies to patients who are *not* prisoners that he sees in his private practice. (Kendig. Dep. pp. 22, 25). Yet he proposes another "correctional standard of care" that is neither scientific, nor sufficient to meet the *Daubert* test. *Kumho Tire v. Carmichael*, 526 US 137 (1999). None of the cases cited by Defendants support intentional departure from the admitted AASLD/IDSA medical standard-of-care in the treatment of HCV. ECF106:16-20.

### 4. Disputed Material Facts Prevent Rule 56 Summary Disposition of this Matter

The foregoing Sections I and II demonstrate that the Court must deny Defendants' Rule 56 motion, in view of the large number of material, disputed facts. *Celotex Corp v.*

*Catrett*, 477 U.S. at 321, *Anderson*, 477 U.S. at 255. And, "genuine issues of material fact" do lie if a jury could conclude for Plaintiff based on "all reasonable evidence to be drawn from those facts." *Matsushita,* 475 U.S. at 587.

On the question of the HCV standard-of-care that applies in prisons, there can be no standard other than that published by the AASLD/IDSA, which governs the provision of HCV medical treatment by providers, for all patients.

### 5. The Eleventh Amendment Does NOT Bar Prospective Injunctive Relief Against DOC Officials Sued in their Official Capacity.

Plaintiffs agree that, in §1983 cases, state officials may be sued in their official capacities for prospective injunctive relief without violating the Eleventh Amendment. See *Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs.,* 443 F.3d 1005, 1017 (8th Cir.2006), vacated on other grounds, ___ U.S. ___, 127 S. Ct. 3000 (2007) (recognizing that only state officials, as opposed to state agencies, can be sued for prospective injunctive relief and dismissing claims against state agency). See also *Kentucky v. Graham,* 473 U.S. 159, 167 n. 14, (1985), *Alabama v. Pugh,* 438 U.S. 781, 781-82, (1978) (same).[16]

As to damages, MNDOC waives sovereign immunity under §504 by accepting federal funds. See *Jim C v. U.S.*, 235 F.3d 1079, 1080 (8th Cir. 2000) (en banc). Title II of the ADA abrogates both the State of Minnesota's and MNDOC's Eleventh Amendment immunity. See *U.S. v. Georgia*, 546 U.S. 151, 159 (2006) (Fourteenth Amendment Due Process Clause incorporates Eighth Amendment guarantee against cruel and unusual punishment).

[16] The 11th Amendment restriction does not apply to §504 or the ADA. See infra.

The conflicting clauses in the contract regarding the standards-of-care for HCV-positive inmates and HIV/AIDS-positive inmates implicate Fourteenth Amendment Due Process and Equal Protection claims.

### 6. Qualified Immunity

Defeat of qualified immunity, which applies to claims for damages in §1983 cases, but not damages in §504 or ADA cases, and does not apply to pursuit of prospective injunctive relief, signals victory on the merits of this motion.

In *White v. Pauley*, 137 S. Ct. 548 (2017), the Court reiterated the longstanding principle that "clearly established law" should not be defined" at a high level of generality." *Ashcroft v. al-Kidd,* 563 U.S. 731, 742 (2011). As the Court explained, the clearly established law must be "particularized" to the facts of the case. *Anderson v. Creighton,* 483 U.S. 635, 640, (1987). Of course, "general statements of the law are not inherently incapable of giving fair and clear warning," *U.S. v. Lanier,* 520 U.S. 259, 271, (1997), but "in the light of pre-existing law the unlawfulness must be apparent," *Anderson v. Creighton, supra,* at 640. As Dr. Kendig testified:

> So, the field of Hepatitis C, I would agree that the Hepatitis C website (http://www.hcvguidelines.org) is the major -- the major for treatment -- is the major source for developing clinical practice guidelines for the correctional setting, but they must be adapted. So to answer your question, are they identical? No. Kendig Dep. p. 22.

Defendants concede, as they must, that the failure to adhere to the AASLD/IDSA standard-of-care was conscious and intentional. Thus, the claims go to trial.

In this case, adhering to the AASLD/IDSA HCV medical treatment community standard-of-care in treating HCV-infected MNDOC patients, as recognized in Contract #

70449 for HIV/AIDS-positive inmates, is exactly such a well-established professional and, in context, constitutional standard that is made particular by the AASLD/IDSA Guidance Panel website. http://www.hcvguidelines.org. In *Erickson v. Pardus*, 551 U.S. 89 (2007), the Supreme Court long ago recognized that Hepatitis C presents a serious medical need and that exposing inmates to Hepatitis C made out a claim for deliberate indifference. *Helling v. McKinney*, 509 U.S. 25, 33 (1993). See similar Eighth Circuit cases, *Moore v. Duffy,* 255 F.3d 543 (8th Cir. 2001); *Burke v. N.D. Dept. of Corr.* 294 F.3d 1043 (2002). According to putative Defendant's expert Dr. Newton Kendig:

> The AASLD (American Association for the Study of Liver Disease and IDSA (Infectious Disease Society of America) recommend that nearly all persons with chronic HCV infection be considered candidates for treatment with DAAs due to the multiple patient benefits and public health advancements associated with curing HCV infection." Kendig Report 8¶4.

There is no dispute that this admitted, nonprioritizing standard-of-care was adopted by the AASLD by June 29, 2015, and certainly no later than the lengthy statement published on November 16, 2015, (Pl. Resp. pp. 11-12). Medical treatment providers are charged with knowing and applying changes in the standards of care, which are more exact requirements than simple differences of opinion between doctors, which was the issue on *Fourte v. Faulkner County*, 746 F.3d 384 (2014).

In this case, the issue is what the medical practitioner *shall* do, when an HCV-positive patient seeks treatment according to the medical standard of care. ECF106:8-12, in contrast to Dr. Thompson, ECF79. Defendants' putative expert does not argue that the standard-of-care is "in flux" ECF106:27; Dr. Kendig concedes the AASLD/IDSA is the medical standard-of-care for all patients (*except* prison inmates):

> A: So, the field of Hepatitis C, I would agree that the Hepatitis C website (http://www.hcvguidelines.org) is the major -- the major for treatment -- is the major source for developing clinical practice guidelines for the correctional setting, but they must be adapted. So to answer your question, are they identical? No. Kendig Dep. p. 22

Plaintiffs and Defendants agree that the AASLD/IDSA standard-of-care is the single standard that applies to all patients outside a "correctional context."

> Q. Would you use the correctional standard of care for treating Hepatitis C patients in a private clinical setting in 2016.
>
> A. *NO.* Id., p 25)

*Meloy v. Bachmeier*, 302 F.3d 845, 849 (8th Cir. 2002), clearly established, again, that a prison official's deliberate indifference to an inmate's serious medical needs violates the Eighth Amendment. See also *Jolly v. Knudsen,* 205 F.3d 1094, 1096 (8th Cir.2000). A supervisor is liable "for an Eighth Amendment violation when the supervisor is personally involved in the violation or when the supervisor's corrective inaction constitutes deliberate indifference toward the violation." *Boyd v. Knox,* 47 F.3d 966, 968 (8th Cir.1995) (footnote omitted). "The supervisor must know about the conduct and facilitate it, approve it, condone it, or turn a blind eye [to it]." Id.

Unlike Bachmeier's role, which was adherence to the order of the doctor in question only, Defendant Larson played an active role in reviewing and denying inmate "kites" and "medical grievances" regarding screening and treatment for HCV. Nanette Larson was involved in the "chain-of-command" and intimately involved in decision-making for HCV screening and treatment. She admitted regular consultation with Dr. Paulson on hepatitis C grievances.

Moreover, the contract with Centurion, which Ms. Larson administered and Dr. Paulson implemented, established two separate standards of care for two chronic, disabling diseases -- HCV and HIV/AIDS -- which stated deliberate indifference, on its face, and authorized un-equal treatment standards for inmates infected with blood-borne disease. Expecting prison medical staff to adhere to the medical treatment community standard of care, as described in Contract # 70449 and the AASLD/IDSA for Hepatitis C, meets the standard of "clearly established law" under *White v. Pauley*, 137 S. Ct. 548 (2017) with the level of specificity required under *Ashcroft v. al-Kidd,* 563 U.S. at 742 (2011).

When the AASLD/IDSA standard-of-care determines the "right" at issue, viz., standard of medical care, there is no dispute that a "reasonable" HCV treatment provider would have known of its existence as did Defendants in this case.

## B. The Threat of Irreparable Harm to the Moving Party

There is no dispute that Ligons, Michaelson, Maxcy, Farley, and unnamed class members yet to be identified, have tested positive for HCV infections, or will test positive, and can be cured of the infection at a 90-95% success rate in 12-weeks with one of the readily available DAA drugs. People infected with HCV can suffer from heart attacks, diabetes, kidney disease, cancers, mental distress, fatigue, joint pain, depression, sore muscles, arthritis, cancers, nerve damage and jaundice. See Cecil Deposition at 48 (1 in 3 chance of death).

The degree of liver scarring is measured by fibrosis score, for "FIB score" with F0 or F1 indicating minimal fibrosis scarring, F2 an intermediate level, F3 severe fibrosis, and F4 "cirrhosis of the liver." "Cirrhosis means scarring of the liver is so extensive it is unable to

carry out its blood cleansing function and the patient faces a terminal prognosis. There is no way to predict how rapidly a patient will progress from F0 to an F4 fibrosis score, once infected with HCV. Delaying treatment until patients reach F3 and F4 scores, or denying treatment to patients below F3 or F4 fibrosis scores, needlessly risks premature death, liver transplant, kidney disease, daily irreversible deterioration of the liver and prolonging suffering associated with HCV. Treatment of HCV in patients with mild liver disease decreases complications and risk of serious liver illness and death. See ECF79, ECF93, Thompson Dep. 118, ECF36, and ECF37.

Both Ligons and Michaelson received prescriptions for treatment with DAA drugs from Dr. Thompson after she interviewed them and reviewed the medical records that were available in October 2016. Thompson Dep. 91:1-25. Defendants' unconstitutional failure to provide the curative DAA medications is a daily threat to Plaintiffs' lives and well-being, *Erickson v. Pardus*, 551 U.S. at 91-92 (2007), as well as the HCV status of others. *Helling,* 509 U.S. at 33 (1993).

There is NO medical justification to ration DAAs using diagnostic Fibrosis Score to limit HCV treatment to F3 and F4 fibrosis scores under the AASLD/IDSA standard of care, *http://www.hcvguidelines.org*, as Dr. Kendig admits in his Deposition, p. 25, would be the case in his private practice. Kendig Dep. p. 25, supra, passim, and where infectiousness is not dependent on FIB4 score.

### C. The Balance of Harms Between the Parties from Granting the Injunction.

From a public health perspective, requiring a doctor merely to observe *any* HCV-infected patient, without treating the disease, makes the doctor complicit in the spread of the epidemic in a prison, or in the public. There is simply no medical justification for observation and delaying treatment of an individual who otherwise meets the AASLD/IDSA/HCV Guidance Panel Guidelines. The current recommendations provide that "[b]ecause of the many benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR, *preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications."http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.*

Providing daily oral medication is a regular function of a correctional facility. Administration of daily DAA medication to HCV-positive patients requires no particular security or administrative arrangements, as the Kendig Report reveals. Assuming *arguendo,* that the Kendig Report met the *Daubert* test for expert evidence regarding a deliberate indifference/medical standard of care issue before the Court, which it does not, Dr. Kendig purports to justify "gradually treating inmates based on disease severity -- i.e. only F3 and F4 levels of fibrosis -- rather than treating all HCV-positive patients as required by the HCV medical treatment community standard of care using the following rationale: Kendig Report, pp.13-14:

(1) correctional systems have a large number of patients;

(2) the logistics are daunting, which will require resources;

(3) the fiscal burden dwarfs previous fiscal burdens;

(4) correctional health administrators operate within fixed budgets, delaying treatment is cost-effective;

(5) correctional health care providers practice population medicine, not community based care.

As discussed in Section III of this Memorandum to Exclude the Kendig Report, the costs of complying with the constitutionally-required HCV medical treatment community standard of care are not a defense to the injunctive relief sought by Plaintiffs. See *Watson v. City of Memphis*, 373 U.S. 526, 537 (1963); *Barron v. Keohane*, 216 F.3d 692 (8th Cir. 2000).

## D. The Public Interest in the Issuance of the Injunction.

### 1. Hepatitis-C is a Widespread Disease.

"Hep-C" has been a growing, "silent epidemic" since it was first discovered in 1989, but blood tests to detect HCV did not exist until 1992. Most of the 3.5 million Americans infected with HCV are not aware of their status and 800,000 Americans with HCV are among the 2 million in prisons and jails. Nearly 20,000 Americans die of HCV-related causes every year, more than from HIV/AIDS. The CDC recommends *all* Americans born before 1965 should be tested for HCV because all are at risk. But, according to the CDC, up to 70% of those with HCV will develop chronic liver disease, 40% will develop cirrhosis, and more than 5% will develop liver cancer. HCV is the most common cause of liver transplants.

### 2. HCV is Contagious in Normal Prison- Life Situations.

HCV spreads when the blood of an infected person enters the body of an uninfected person. This can occur by sharing body fluids with non-sterile medical equipment, sex,

sharing needles, getting tattoos, bloody fights or sports injuries. Transmission can occur through: razors; nail clippers: barbers' or stylists' scissors; toothbrushes; blood drops on surfaces; and, diabetic glucose monitors.

### 3. Individuals Not Treated Promptly Threaten Others with HCV Infection Both in Prison, and Upon Release from Prison.

HCV-positive individuals living in a confined environment, such as a jail or prison, are at greater risk of transmission of HCV than persons in the general population. The close proximity of HCV infected individuals in situations in which transfer of blood products might occur is also much higher in jail and prison settings. Whether a patient's fibrosis level is F0 or F4, the infected individual has the same potential for infecting those with whom they come in contact.

### 4. Eradicating the HCV Epidemic: Clearing HCV from Prison Blood Pools, to clear the Nation's Blood Pool.

Both the CDC and World Health Organization (WHO) have designated the elimination of the HCV virus a goal that can be achieved in the same way that polio was defeated worldwide, by cleansing the human blood pool of the virus wherever it can be found today.

### 5. DAA Treatment is Cost Effective.

See ECF79 and ECF93. Treatment of HCV with DAAs is cost-effective, overall. There have been a variety of studies examining the cost effectiveness of DAAs to the health care system.

## IV. RULE 23 CLASS CERTIFICATION

### A. HCV in Minnesota Prisons

Ten (10) to 35 percent (1000 to 3500) of the estimated 10,000 inmates under the supervision of the Minnesota Department of Corrections (MNDOC) are currently infected with HCV. See, *Health Services Unit*, "Chronic Hepatitis C Management & Procedures, 5/9/2012 - distributed June 2015).[17] By intentionally denying the HCV medical treatment community standard of care, Defendants' threaten Plaintiffs and those similarly situated with death and other irreparable harm stemming from their HCV infections. Members of the proposed class and sub-classes have suffered and will continue to suffer grave and irreparable harm.

### B. AASLD/IDSA Standard of HCV Care

Defendants admit the American Association for the Study of Liver Disease (AASLD)/Infectious Disease Society of America (IDSA) standard of care for HCV-positive patients requires that direct acting anti-viral (DAA) drugs be prescribed for "nearly all persons with chronic HCV infection," *http://hcvguidlines.org/full-report,* Kendig Report p.8¶4 (concurs).

The AASLD/IDSA is also referenced as the HCV standard of care by Dr. Newton Kendig, Defendants' proposed expert witness. *http://hcvguidelines.org/full-report/when-*

[17] Defendants claim April 2015 HCV Guidelines were issued "in response to the new crop of DAAs," (ECF106:8). However, the documentary record shows Plaintiffs were provided the document marked June 2015, referring to 2012. There is a material factual dispute regarding the MNDOC standards before January 16, 2016, the date of the current protocol, and 12 days after the deadline to amend pleading and join additional parties

*and-whom-initiate-hcv-therapy.*[18] Those specify the most recently approved DAA drugs are the standard of medical care for the treatment of HCV, irrespective of fibrosis score, and that treatment NOT be reserved for patients with F3 and F4 fibrosis scores. Prescribing DAA treatment for all HCV-infected patients is the standard-of-care in the HCV medical treatment community, *which is to be distinguished from the non-medical third-party payer.*

### B. Defendants Admit the January 2016 MNDOC HCV Treatment Protocols Fail to Meet the AASLD/IDSA Standard of Care.

The HCV treatment protocols adopted January 2016, MNDOC purports to treat only inmates that have progressed to F3 or F4 fibrosis levels . See, *Minnesota Department of Corrections Guidelines for the Evaluation and Treatment of Chronic Hepatitis C (HCV) Infection,* January 16, 2016, Paulson Aff. Exhibit F. This lawsuit seeks injunctive relief on behalf of a class that includes thousands of prisoners subject to the DOC's unconstitutional medical policy. Specifically, plaintiffs ask the Court to order the DOC to provide prisoners with HCV treatment meeting the AASLD/IDSA standard of care, including but not limited to treatment with the newest DAA drugs.

### D. Proposed Classes and Representatives:

**Devon Farley and Lawrence Maxcy are** HCV-positive inmates of MNDOC with more than two years remaining on their respective sentences who have not been treated for their HCV infection despite numerous requests and having exhausted administrative

[18] Harvoni and Viekira-Pak were FDA-approved in October 2014 and adopted as the AASLD/IDSA standard-of-care, without interferon injections in January 2015, *http://hcvguidelines.org/full-report.*

remedies were formerly unnamed members of the class represented by Mr. Ligons and Mr. Michaelson.

**Ronaldo Ligons is** an HCV-positive inmate of MNDOC being treated with Zepatier, and with more than two years remaining to serve on his sentence who has been treated for his HCV infection and, like other HCV uninfected inmates, wishes to avoid re-infection by untreated HCV inmates to whom he is exposed in MNDOC facilities because of the failure to adopt AASLD/IDSA standards-of-care by MNDOC. He represents hitherto-pseudonymous Miles and Stiles.

**Barry Michaelson** represents individuals who were incarcerated at the start of the lawsuit, and are still infected, whether they are still incarcerated or not.

## E. The Standard for Class Certification

The class action serves to conserve "the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion under Rule 23." *Gen. Tel. Co. of the Southwest v. Falcon*, 457 U.S. 147, 155 (1982), *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011). Pursuant to Rule 23(a), there are four threshold requirements to class certification: (1) the putative class is so numerous that it makes joinder of all members impractical; (2) questions of law or fact are common to the class; (3) the class representatives' claims or defenses are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class. *In re St. Jude Med., Inc.*, 425 F.3d 1116, 1119 (8th Cir. 2005) (citing Fed. R. Civ. P. 23(a)) (footnote and other citations omitted).

If these prerequisites are met, the Court must then determine if the putative class is maintainable under Rule 23(b). Rule 23(b)(1) allows a class action when "prosecuting separate actions by or against individual class members would create a risk of: (A) inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party opposing the class; (B) or (C) are not applicable here. The Eighth Circuit has recognized that prison condition civil rights claims are particularly well-suited to class-action claims. *Coley v. Clinton*, 636 F.2d 1364, 1378 (8th Cir. 1980).

Plaintiffs seek to certify a class of: (a) MNDOC inmates known to have been HCV-positive on or after the date of the filing of this action, May 1, 2015, who have not been treated with the curative direct acting anti-viral (DAA) drugs required by the AASLD/IDSA standard of care; (b) formerly-incarcerated MNDOC inmates known to have been HCV-positive as of the date of the filing of this action, May 1, 2015, who have not been treated with the curative DAA drugs; (c) current MNDOC inmates who do not know their HCV status, or who are HCV-negative, and wish to be avoid be infected or re-infected with HCV.

i. **The Class is so Numerous that Joinder is Impracticable.**

The class of more than one thousand MNDOC HCV-positive inmates known to Defendants, the specific identity of each is within the knowledge of Defendants, meets the numerosity requirement of Rule 23(a)(l), which requires that the class be so numerous that joinder of all class members would be impracticable. Plaintiffs are completely under the day-to-day control of Defendant MNDOC. Impracticability of joinder does not mean impossibility, only that joinder would be difficult. *Sanft v. Winnebago Indus., Inc.* 214

F.R.D. 514 (2003). ("[Under Rule 23(a)(l)], [t]he plaintiff need not precisely enumerate the potential size of the proposed class, nor is the plaintiff required to demonstrate that joinder would be impossible."); see also 7A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1762 (3d ed. 2005) ("'Impracticable' does not mean 'impossible.' *Emmanuel v. Marsh*, 828 F.2d 438, 444 (8th Cir. 1987).

### ii. Members of Each Sub-Class Have Questions of Law and Fact in Common

Rule 23(a)(2) requires that in order for a class to be certified "there are questions of law or fact common to the class, and the rule "may be satisfied, for example, where the question of law linking the class members is substantially related to the resolution of the litigation even though the individuals are not identically situated." *Paxton v. Union Nat'l Bank,* 688 F.2d 552, 561 (8th Cir. 1982) (citation omitted). " Commonality requires the plaintiffs to demonstrate that the class members have suffered the same injury." *Ebert v. Gen. Mills*, 823 F.3d 472, 478 (8th Cir. 2016). If the same evidence on an issue can suffice for each class member, then it is a common question, *Blades v. Monsanto Co.*, 400 F.3d 562, 566 (8th Cir. 2005), this includes:

- Plaintiffs are the object of the common HCV protocols imposed upon them by Defendants before and after January 2016;
- Defendants have admitted that the AASLD/IDSA standard of care is applicable to all HCV-positive patients, who are not prisoners;
- Defendants have asserted a "correctional standard of care" for HCV that purports to apply generally to the prison population;
- the "deliberate indifference" standard of *Estelle v. Gamble* applies to the HCV treatment protocols adopted by Defendants;

- whether the *Kendig Report* should be excluded from evidence under Daubert;

Moreover, actions seeking an injunction against a common policy imposed on incarcerated inmates have been found to raise common questions in this Circuit. *Coley v. Clinton*, 636 F.2d 1364, 1378 (8th Cir. 1980) (reversing district court's denial of class certification for a class on commonality and typicality when plaintiff alleged common threat of injury to incarcerated population).

The U.S. District Court in Massachusetts has already certified a class action for treatment of HCV-infected Massachusetts Department of Corrections inmates. *Fowler v. Turco*, 15-cv-12298 (D. Mass. July 22, 2016), ECF48. With class certification pending in Tennessee, *Graham v. Parker*, 16-cv-1954 (Order, D. M.D. Tenn. Feb. 27, 2017), ECF28, with that Court's open acknowledge of the need for medical monitoring as a remedy ("However, given the nature of the case, settlement discussion will of necessity involve medical personnel and potentially the need for monitoring by some designated agency[,]"), these case drive the stake into the Defendants' arguments against class certification under the PLRA.

### iii. The Claims of the Named Plaintiffs are Typical of Those of the Class

Rule 23(a)(3) requires that in order for a class to be certified, the claims or defenses of the class representative must be typical of the class. Fed. R. Civ. P. 23(a)(3). Typicality is generally met "if the claims or defenses of the representatives and the members of the class

stem from a single event or are based on the same legal or remedial theory." *Paxton v. Union Nat'l Bank*, 688 F.2d 552, 561-62 (8th Cir. 1982) (citations omitted).

Plaintiffs satisfy the typicality prong because their claims "stem from the same facts . . . and the same theory." *Kimball v. Frederick J. Hanna & Assoc., P.C.*, 10-cv-130, __, 2011 WL 3610129, at *4 (D. Minn. Aug. 15, 2011) MJD/JJG.

Typicality is satisfied because the Defendants have applied the same HCV treatment protocols to all MNDOC patient/inmates and the claims stem from a set of facts that is common to every Class Member. See *DeBoer v. Mellon Mortgage Co.*, 64 F.3d 1171, 1174-75 (8th Cir. 1995) (typicality was satisfied because the Class Members sought the same relief, even if the amount of damages was different). Thus, this class meets the 23(a)(3) typicality requirement.

### iv. The Plaintiffs Will Fairly and Adequately Protect the Interests of the Class.

Rule 23(a)(4) requires that in order for a class to be certified the Court must determine whether the named representative and her counsel will adequately represent the interests of the class members. Fed. R. Civ. P. 23(a)(4). The adequacy requirement is satisfied when the class representative is "part of the class and possess[es] the same interest and suffer[s] the same injury as the class members." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 594-95 (1997). "The district court must decide whether Rule 23(a)(4) is satisfied through balancing the convenience of maintaining a class action and the need to guarantee adequate representation to the class members." *Rattray v. Woodbury Cnty., IA*, 614 F.3d 831, 835 (8th Cir. 2010).

The Court must "evaluate carefully the legitimacy of the named plaintiff's plea that he is a proper class representative under Rule 23(a)." *In re Milk Prods. Antitrust Litig.*, 195 F.3d 430, 436 (8th Cir. 1999). The adequacy inquiry has two components: (1) whether the attorneys retained by the named plaintiffs are qualified, experienced, and generally able to conduct the litigation; and (2) whether the named plaintiffs have interests that are antagonistic or in conflict with those they seek to represent. *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 313 (3d Cir. 2007); *Kalow & Springut, LLP v. Commence Corp.*, 272 F.R.D. 397, 405 (D.N.J. 2011).

(1) Plaintiffs' attorneys are qualified and experienced in conducting class action prisoners' rights litigation.

Counsel retained by the named plaintiffs are qualified and generally able to conduct the litigation.

1. Professor Erlinder has represented Mr. Ligons as a client for over twenty years in a number of cases. He continues his service to Mr. Ligons in representing him in this lifesaving litigation.
2. Plaintiffs' counsel have no comparison in the Minnesota legal community as attorneys who have committed themselves to the study of Hepatitis C and its effect upon Minnesota community.
3. Plaintiffs' counsel have brought this case to the attention of counsel from larger firms with class action experience. One of these firms has expressed interest in association as class counsel should this Court grant the Plaintiffs' preliminary injunction motion.

4. Plaintiffs' counsel have limited experience in class litigation. Mr. Nickitas associated with Messrs. Tommy Lyons, Sr. and Tommy Lyons, Jr. in the prospective consumer class action, *Scheffler v. Integrity Partners*, 12-cv-188 (D. Minn. 2013), settled after filing appeal, (8th Cir. Aug. 18, 2014); the district court did not grant class certification and the case settled before appellate oral argument.
5. Mr. Nickitas represented over twenty Plaintiffs in the non-class action ERISA case of *Blaine et al. v. LTV Steel Mining Co.*, 97-cv-1475 (D. Minn. 1999) MJD/JGL, while associating with the firm of Mansfield, Tanick, and Cohen, P.A. Mr. Nickitas' duties included periodic trips to the Iron Range to serve the retired miner clients, defended all miners' depositions, and traveled to Cleveland, OH to take LTV officials' depositions. The case settled before Magistrate Judge Lebedoff in a settlement conference in 1999.

(2) Plaintiffs do not have any interests antagonistic to those of any other member of the proposed class. Antagonism may exist between the named plaintiff and other class members when a unique defense could be asserted against a plaintiff that would distract from the class claims or defenses. No such circumstances are present here. On the contrary, the Plaintiffs' interests coincide with those of the proposed class to seek a declaration that the policies, patterns, and practices alleged in the complaint are unconstitutional as well as a permanent injunction prohibiting Defendants from further implementing such patterns, practices, and policies. The granting of the relief sought by Plaintiffs would benefit the class members and would not impair any future class member's claims. Accordingly, this class meets the 23(a)(4) adequacy requirement.

## C. The Plaintiffs Meet the Requirement of Rule 23(b)(2).

Plaintiffs properly seek certification pursuant to Rule 23(b)(2), which provides that a class action is appropriate when "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2). As the Supreme Court has explained: The key to the (b)(2) class is "the indivisible nature of the injunctive or declaratory remedy warranted-the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them." *Wal-Mart Stores, Inc.,* 131 S. Ct. at 2557 (citation omitted).

Further, Rule(b)(2) is especially appropriate for Prisoners' civil rights actions like this one because of the potential for common resolution through declaratory and injunctive relief. *See Coley,* 635 F.2d 1364 at 1378 (certifying class of inmates at a state hospital, noting Rule 23(b)(2) class actions are "especially appropriate vehicles for civil rights actions seeking such declaratory relief for prison and hospital reform"); *Clarkson v. Coughlin*, 783 F. Supp. 789, 797 (S.D.N.Y. 1992) ("[t]he class action device is particularly well-suited in actions brought by prisoners"). See *Parsons v. Ryan*, 289 F.R.D. 513, 515, 524 (D. Ariz. 2013) (granting Rule 23(b )(2) certification for a class of inmates challenging inadequate prison medical, dental, and mental health care services).

Here, Plaintiffs' claims are so inherently intertwined as a result of Defendants' policy and practice of not treating Hepatitis C that injunctive and declaratory relief as to any would be injunctive and declaratory relief to all. ("...one purpose of Rule 23(b)(2) was to enable plaintiffs to bring lawsuits vindicating civil rights, the rule "must be read liberally in

the context of civil rights suits." *Ahrens v. Thomas*, 570 F.2d 286, 288 (8th Cir. 1978). See generally 7A C. Wright & A. Miller, *Federal Practice & Procedure* §§ 1775-1776 (1972).

## VI. REHABILITATION ACT and ADAA

The Defendants' arguments against Plaintiffs' ADA and §504 claims are misplaced. The discriminatory denial of the standard of medical care for curable HCV, in comparison to the Defendants' provision of the standard of medical care for incurable HIV/AIDS, denies Fourteenth Amendment equal protection, for which §1983 provides legal and equitable remedies, and which runs afoul of discriminatory denial of the public program of prison medical care because of the Plaintiffs' disability, HCV.

In *Dinkins v. Correctional Medical Services (CMS)*, 743 F.3d 633 (8th Cir 2014) Dinkins sued the State of Missouri, the Missouri DOC, unnamed medical doctors, and Jefferson City Correctional Center officers in their official and individual capacities for violations of §504 Title II. The Court reversed the dismissal of claims for injunctive relief against individual officials, the State of Missouri and MNDOC that were not based on medical treatment decisions. *See Hafer v. Melo*, 502 U.S. 21, 25 (1991) (official-capacity claims are another way of pleading the action against the State), *Randolph v. Rodgers*, 253 F.3d 342, 348 (8th Cir. 2001) (permitting claims for prospective injunctive relief against a state official sued in official capacity under ADA and RA); 42 U.S.C. §12202 (ADA statute abrogating state sovereign immunity provides that "remedies (including remedies both at law and in equity are available"); 42 U.S.C. §2000d-7(a)(2) (same for §504).

Title II of the ADA applies to an "individual with a disability who. . . meets the essential eligibility requirements for the receipt of services or the participation in programs

or activities provided by a public entity." 42 U.S.C. § 12131(2). Title II of the ADA extends to prison inmates deprived of the benefits of participation in prison programs, services, or activities because of a disability. *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 211 (1998) The ADA and the Rehabilitation Act are congruent statutes in purpose and application. *Clark v. Cal.*, 123 F.3d 1267, 1270 (9th Cir. 1997).

To establish an ADA or §504 claim, the plaintiff must show (1) he is a qualified individual with a disability; (2) he was either excluded from participation in or denied the benefits of a public entity's services, programs or activities, or was otherwise discriminated against by the public entity; and (3) such exclusion, denial of benefits, or discrimination was by reason of his disability. Id. See also *Innovative Health Sys., Inc. v. City of White Plains*, 117 F.3d 37, 45 (2d Cir. 1997) (reasoning that the phrase "programs, services, or activities" is "a catch-all phrase that prohibits all discrimination by a public entity, regardless of the context"), superseded on other grounds, *Zervos v. Verizon New York, Inc.*, 252 F.3d 163, 171 n. 7 (2d Cir. 2001).

While a individual medical treatment decision may not make out a cause of action under §504 or Title II, *Shelton v. Arkansas Dept. of Public Services*, 677 F.3d 837 (8th Cir. 2012), the conscious, discriminatory refusal of the Defendants to adopt the AASLD/IDSA standard-of-care for curable, but disabled HCV-infected inmates, in contrast to the application of the standard of medical care for incurable, disabled HIV-positive inmates, is a matter of policy -- not just an individual treatment decision, and it manifests Defendants' conscious adoption of the policy of discriminating against inmates

because of their disability, HCV, and exposing uninfected prisoners to HCV-positive inmates.

The failure to provide the medical standard-of-care for HCV while requiring the medical standard-of-care for HIV/AIDS infected prisoners, permits the physical deterioration of the entire prison population, and is not a medical treatment decision *per se*. The contract between MNDOC and Centurion implicates Fourteenth Amendment Due Process and Equal Protection violations by preventing HCV-positive inmates from receiving the same "medical community standard-of-care" that HIV/AIDS-positive inmates receive.

As to the request for damages arising from this policy, MNDOC waived sovereign immunity under §504 by accepting federal funds. *See Jim C. v. United States*, 235 F.3d 1079, 1080 (8th Cir. 2000) (en banc). Title II abrogates both the State of Minnesota and the MNDOC's immunity for conduct that actually violates the Fourteenth Amendment. *See U.S. v. Georgia*, 546 U.S. at 159 (Fourteenth Amendment Due Process Clause incorporates Eighth Amendment guarantee against cruel and unusual punishment).

As in *Helling v. McKinney*, 509 U.S. 25, 33 (1993), and *Dinkins v. CMS*, 743 F.3d 633 (8th Cir 2014), denial of safe HCV-free living conditions and participation in prison programs without risk of HCV exposure can form the basis for viable ADA and §504 claims. *See Pa. Dep't of Corr. v. Yeskey,* 524 U.S. 206, 210, (1998) (recreational activities, medical services, and educational and vocational programs at state prisons are benefits within the meaning of ADA); *Jaros v. Ill. Dep't of Corr.,* 684 F.3d 667, (7th Cir.2012) (meals and showers made available to inmates are programs or activities under §504).

At the very least, Plaintiffs survive summary judgment on their §504 and ADA claims.

## VII. CONCLUSION

The case begins and ends with the AASLD/IDSA professional medical standard of care for Hepatitis C patients. Defendants' Hepatitis C protocol manifested, when they did not attempt to conceal, unconstitutional, deliberate indifference to the serious medical needs of named and unnamed infected inmates, numbering in the hundreds if not thousands and named and unnamed inmates numbering in the thousands, who want to be free from infection, more especially in the new era of medicines that cure Hepatitis C 95%+ of the time without side effects.

The Defendants' discriminatory denial of the professional medical standard of care for a curable, disabling disease, Hepatitis C, in favor of provision of the professional standard of medical care for a chronic, incurable disabling disease, HIV/AIDS, is irrational and violates §504 and ADA Title II.

Defendants' Dr. Kendig has no place to lecture this Court on constitutional law with arguments lacking scientific foundation.

Prospective injunctive relief in treatment and testing are proper remedies under §1983 against these official capacity Defendants, and proper under §504 and Title II against the state as well. The Court should see Defendants' arguments for what they are, bad science and cruel, unconstitutional public policy. Medicine, science, law, public interest, and fulfillment of Matthew 25:33-40 in the secular world of prisons favor the Plaintiffs.

The Court should deny the Defendants Rule 56 motion, grant Plaintiffs' motion for preliminary injunction and partial summary judgment as to liability on the standard of care,

certify the classes of current inmates seeking HCV treatment, inmates at the start of the lawsuit who still seek treatment, and inmates who want to remain free from infection, and exclude Dr. Kendig as a defense expert per *Daubert.*

Date: 26 April 2017

Respectfully submitted:

PETER J. NICKITAS LAW OFFICE, L.L.C.

/s/ *Peter J. Nickitas* (electronically signed)

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